

108TH CONGRESS
1ST SESSION

H. R. 1199

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 11, 2003

Mr. RANGEL (for himself, Mr. DINGELL, Mr. HOLDEN, Mr. BROWN of Ohio, Mr. STARK, Mr. WAXMAN, Mr. PALLONE, Mr. ABERCROMBIE, Mr. ACKERMAN, Mr. ALEXANDER, Mr. ALLEN, Mr. ANDREWS, Ms. BALDWIN, Mr. BECERRA, Mr. BELL, Ms. BERKLEY, Mr. BERMAN, Mr. BERRY, Mr. BISHOP of New York, Mr. BOSWELL, Mr. BOUCHER, Ms. CORRINE BROWN of Florida, Mrs. CAPPS, Mr. CAPUANO, Mr. CARDIN, Mr. CARDOZA, Mrs. CHRISTENSEN, Mr. CLAY, Mr. CONYERS, Mr. CROWLEY, Mr. CUMMINGS, Mr. DAVIS of Illinois, Mr. DELAHUNT, Ms. DELAURO, Mr. DEUTSCH, Mr. DICKS, Mr. DOYLE, Mr. ENGEL, Mr. EVANS, Mr. FARR, Mr. FILNER, Mr. FRANK of Massachusetts, Mr. FROST, Mr. GEPHARDT, Mr. GORDON, Mr. GREEN of Texas, Mr. GRIJALVA, Mr. HASTINGS of Florida, Mr. HINCHEY, Mr. HINOJOSA, Mr. HOFFEL, Mr. HOYER, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. KANJORSKI, Ms. KAPTUR, Mr. KENNEDY of Rhode Island, Mr. KILDEE, Ms. KILPATRICK, Mr. KLECZKA, Mr. LAMPSON, Mr. LANGEVIN, Mr. LANTOS, Mr. LARSON of Connecticut, Ms. LEE, Mr. LEVIN, Mr. LEWIS of Georgia, Mrs. LOWEY, Mr. LYNCH, Mrs. MALONEY, Mr. MARKEY, Mr. MATSUI, Ms. MCCARTHY of Missouri, Ms. MCCOLLUM, Mr. McDERMOTT, Mr. MCGOVERN, Mr. McNULTY, Mr. MEEHAN, Mr. MEEK of Florida, Mr. MEEKS of New York, Ms. MILLENDER-McDONALD, Mr. GEORGE MILLER of California, Mr. MOLLOHAN, Mr. MURTHA, Mr. NADLER, Mrs. NAPOLITANO, Mr. NEAL of Massachusetts, Ms. NORTON, Mr. OBERSTAR, Mr. OLVER, Mr. ORTIZ, Mr. OWENS, Ms. PELOSI, Mr. RAHALL, Mr. REYES, Mr. RODRIGUEZ, Mr. ROSS, Ms. ROYBAL-ALLARD, Mr. RUSH, Ms. LINDA T. SÁNCHEZ of California, Mr. SANDERS, Mr. SANDLIN, Ms. SCHAKOWSKY, Mr. SCHIFF, Mr. SCOTT of Virginia, Mr. SERRANO, Ms. SLAUGHTER, Ms. SOLIS, Mr. STRICKLAND, Mr. THOMPSON of Mississippi, Mr. TIERNEY, Mr. TOWNS, Mrs. JONES of Ohio, Mr. UDALL of New Mexico, Mr. VAN HOLLEN, Mr. VISCLOSKEY, Ms. WATSON, Mr. WEINER, Mr. WEXLER, Ms. WOOLSEY, and Mr. WYNN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee

on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for a voluntary Medicare prescription medicine benefit, to provide greater access to affordable pharmaceuticals, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*
 3 **SECTION 1. SHORT TITLE; REFERENCES IN ACT; TABLE OF**
 4 **CONTENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
 6 “Medicare Rx Drug Benefit and Discount Act of 2003”.

7 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Ex-
 8 cept as otherwise specifically provided, whenever in this
 9 Act an amendment is expressed in terms of an amendment
 10 to or repeal of a section or other provision, the reference
 11 shall be considered to be made to that section or other
 12 provision of the Social Security Act.

13 (c) TABLE OF CONTENTS.—The table of contents of
 14 this Act is as follows:

TITLE I—MEDICARE PRESCRIPTION MEDICINE BENEFIT

Sec. 101. Voluntary medicare outpatient prescription medicine program.

“PART D—VOLUNTARY PRESCRIPTION MEDICINE BENEFIT FOR THE AGED
AND DISABLED

“Sec. 1859. Medicare outpatient prescription medicine benefit.
 “Sec. 1859A. Negotiating fair prices with pharmaceutical manufacturers.
 “Sec. 1859B. Contract authority.
 “Sec. 1859C. Eligibility; voluntary enrollment; coverage.
 “Sec. 1859D. Provision of, and entitlement to, benefits.
 “Sec. 1859E. Administration; quality assurance.
 “Sec. 1859F. Federal Medicare Prescription Medicine Trust Fund.
 “Sec. 1859G. Compensation for employers covering retiree medicine costs.
 “Sec. 1859H. Medicare Prescription Medicine Advisory Committee.
 Sec. 102. Provision of medicare outpatient prescription medicine coverage
 under the Medicare+Choice program.
 Sec. 103. Medigap revisions.
 Sec. 104. Transitional assistance for low income beneficiaries.
 Sec. 105. Expansion of membership and duties of Medicare Payment Advisory
 Commission (MedPAC).

TITLE II—AFFORDABLE PHARMACEUTICALS

Subtitle A—Greater Access to Affordable Pharmaceuticals

Sec. 201. Accelerated generic drug competition.
 Sec. 202. Patent certification.
 Sec. 203. Additional uses.

Subtitle B—Notification of Agreements Affecting the Sale or Marketing of Generic Drugs

Sec. 211. Definitions.
 Sec. 212. Notification of agreements affecting the sale or marketing of generic
 drugs.
 Sec. 213. Filing deadlines.
 Sec. 214. Enforcement.
 Sec. 215. Rulemaking.
 Sec. 216. Effective dates.

1 **TITLE I—MEDICARE PRESCRIP-** 2 **TION MEDICINE BENEFIT**

3 **SEC. 101. VOLUNTARY MEDICARE OUTPATIENT PRESCRIP-** 4 **TION MEDICINE PROGRAM.**

5 (a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et
 6 seq.) is amended—

7 (1) by redesignating section 1859 and part D
 8 as section 1858 and part E, respectively; and

9 (2) by inserting after part C the following new
 10 part:

1 “PART D—VOLUNTARY PRESCRIPTION MEDICINE
 2 BENEFIT FOR THE AGED AND DISABLED

3 “MEDICARE OUTPATIENT PRESCRIPTION MEDICINE
 4 BENEFIT

5 “SEC. 1859. Subject to the succeeding provisions of
 6 this part, the voluntary prescription medicine benefit pro-
 7 gram under this part provides the following:

8 “(1) PREMIUM.—The monthly premium is \$25.

9 “(2) DEDUCTIBLE.—The annual deductible is
 10 \$100.

11 “(3) COINSURANCE.—The coinsurance is 20
 12 percent.

13 “(4) OUT-OF-POCKET LIMIT.—The annual limit
 14 on out-of-pocket spending on covered medicines is
 15 \$2,000.

16 “NEGOTIATING FAIR PRICES WITH PHARMACEUTICAL
 17 MANUFACTURERS

18 “SEC. 1859A. (a) AUTHORITY TO NEGOTIATE
 19 PRICES WITH MANUFACTURERS.—The Secretary shall,
 20 consistent with the requirements of this part and the goals
 21 of providing quality care and containing costs under this
 22 part, negotiate contracts with manufacturers of covered
 23 outpatient prescription medicines that provide for the
 24 maximum prices that may be charged to individuals en-
 25 rolled under this part by participating pharmacies for dis-
 26 pensing such medicines to such individuals.

1 “(b) PROMOTION OF BREAKTHROUGH MEDICINES.—
2 In conducting negotiations with manufacturers under this
3 part, the Secretary shall take into account the goal of pro-
4 moting the development of breakthrough medicines (as de-
5 fined in section 1859H(b)).

6 “CONTRACT AUTHORITY

7 “SEC. 1859B. (a) CONTRACT AUTHORITY.—

8 “(1) IN GENERAL.—The Secretary is respon-
9 sible for the administration of this part and shall
10 enter into contracts with appropriate pharmacy con-
11 tractors on a national or regional basis to administer
12 the benefits under this part.

13 “(2) PROCEDURES.—The Secretary shall estab-
14 lish procedures under which the Secretary—

15 “(A) accepts bids submitted by entities to
16 serve as pharmacy contractors under this part
17 in a region or on a national basis;

18 “(B) awards contracts to such contractors
19 to administer benefits under this part to eligible
20 beneficiaries in the region or on a national
21 basis; and

22 “(C) provides for the termination (and
23 nonrenewal) of a contract in the case of a con-
24 tractor’s failure to meet the requirements of the
25 contract and this part.

1 “(3) COMPETITIVE PROCEDURES.—Competitive
2 procedures (as defined in section 4(5) of the Office
3 of Federal Procurement Policy Act (41 U.S.C.
4 403(5))) shall be used to enter into contracts under
5 this part.

6 “(4) TERMS AND CONDITIONS.—Such contracts
7 shall have such terms and conditions as the Sec-
8 retary shall specify and shall be for such terms (of
9 at least 2 years, but not to exceed 5 years) as the
10 Secretary shall specify consistent with this part.

11 “(5) USE OF PHARMACY CONTRACTORS IN
12 PRICE NEGOTIATIONS.—Such contracts shall require
13 the contractor involved to negotiate contracts with
14 manufacturers that provide for maximum prices for
15 covered outpatient prescription medicines that are
16 lower than the maximum prices negotiated under
17 section 1859A(a), if applicable. The price reductions
18 shall be passed on to eligible beneficiaries and the
19 Secretary shall hold the contractor accountable for
20 meeting performance requirements with respect to
21 price reductions and limiting price increases.

22 “(6) AREA FOR CONTRACTS.—

23 “(A) REGIONAL BASIS.—

24 “(i) IN GENERAL.—Except as pro-
25 vided in clause (ii) and subject to subpara-

graph (B), the contract entered into between the Secretary and a pharmacy contractor shall require the contractor to administer the benefits under this part in a region determined by the Secretary under subparagraph (B) or on a national basis.

“(ii) PARTIAL REGIONAL BASIS.—

“(I) IN GENERAL.—If determined appropriate by the Secretary, the Secretary may permit the benefits to be administered in a partial region determined appropriate by the Secretary.

“(II) REQUIREMENTS.—If the Secretary permits administration pursuant to subclause (I), the Secretary shall ensure that the partial region in which administration is effected is no smaller than a State and is at least the size of the commercial service area of the contractor for that area.

“(B) DETERMINATION.—

“(i) IN GENERAL.—In determining regions for contracts under this part, the Secretary shall—

1 “(I) take into account the num-
2 ber of individuals enrolled under this
3 part in an area in order to encourage
4 participation by pharmacy contrac-
5 tors; and

6 “(II) ensure that there are at
7 least 10 different regions in the
8 United States.

9 “(ii) NO ADMINISTRATIVE OR JUDI-
10 CIAL REVIEW.—The determination of ad-
11 ministrative areas under this paragraph
12 shall not be subject to administrative or ju-
13 dicial review.

14 “(7) SUBMISSION OF BIDS.—

15 “(A) SUBMISSION.—

16 “(i) IN GENERAL.—Subject to sub-
17 paragraph (B), each entity desiring to
18 serve as a pharmacy contractor under this
19 part in an area shall submit a bid with re-
20 spect to such area to the Secretary at such
21 time, in such manner, and accompanied by
22 such information as the Secretary may rea-
23 sonably require.

24 “(ii) BID THAT COVERS MULTIPLE
25 AREAS.—The Secretary shall permit an en-

1 tity to submit a single bid for multiple
2 areas if the bid is applicable to all such
3 areas.

4 “(B) REQUIRED INFORMATION.—The bids
5 described in subparagraph (A) shall include—

6 “(i) a proposal for the estimated
7 prices of covered outpatient prescription
8 medicines and the projected annual in-
9 creases in such prices, including the addi-
10 tional reduction in price negotiated below
11 the Secretary’s maximum price and dif-
12 ferentials between preferred and nonpre-
13 ferred prices, if applicable;

14 “(ii) a statement regarding the
15 amount that the entity will charge the Sec-
16 retary for administering the benefits under
17 the contract;

18 “(iii) a statement regarding whether
19 the entity will reduce the applicable coin-
20 surance percentage pursuant to section
21 1859E(a)(1)(A)(ii) and if so, the amount
22 of such reduction and how such reduction
23 is tied to the performance requirements de-
24 scribed in subsection (c)(4)(A)(ii);

1 “(iv) a detailed description of the per-
2 formance requirements for which the ad-
3 ministrative fee of the entity will be subject
4 to risk pursuant to subsection (c)(4)(A)(ii);

5 “(v) a detailed description of access to
6 pharmacy services provided by the entity,
7 including information regarding whether
8 the pharmacy contractor will use a pre-
9 ferred pharmacy network, and, if so, how
10 the pharmacy contractor will ensure access
11 to pharmacies that choose to be outside of
12 that network, and whether there will be in-
13 creased cost-sharing for beneficiaries if
14 they obtain medicines at such pharmacies;

15 “(vi) a detailed description of the pro-
16 cedures and standards the entity will use
17 for—

18 “(I) selecting preferred prescrip-
19 tion medicines; and

20 “(II) determining when and how
21 often the list of preferred prescription
22 medicines should be modified;

23 “(vii) a detailed description of any
24 ownership or shared financial interests
25 with pharmaceutical manufacturers, phar-

1 macies, and other entities involved in the
2 administration or delivery of benefits under
3 this part as proposed in the bid;

4 “(viii) a detailed description of the en-
5 tity’s estimated marketing and advertising
6 expenditures related to enrolling and re-
7 taining eligible beneficiaries; and

8 “(ix) such other information that the
9 Secretary determines is necessary in order
10 to carry out this part, including informa-
11 tion relating to the bidding process under
12 this part.

13 The procedures under clause (vi) shall include
14 the use of a pharmaceutical and therapeutics
15 committee the members of which include prac-
16 ticing pharmacists.

17 “(8) AWARDING OF CONTRACTS.—

18 “(A) NUMBER OF CONTRACTS.—The Sec-
19 retary shall, consistent with the requirements of
20 this part and the goals of providing quality care
21 and of containing costs under this part, award
22 in a competitive manner at least 2 contracts to
23 administer benefits under this part in each area
24 specified under paragraph (6), unless only 1
25 pharmacy contractor submitting a bid meets the

1 minimum standards specified under this part
2 and by the Secretary.

3 “(B) DETERMINATION.—In determining
4 which of the pharmacy contractors that sub-
5 mitted bids that meet the minimum standards
6 specified under this part and by the Secretary
7 to award a contract, the Secretary shall con-
8 sider the comparative merits of each bid, as de-
9 termined on the basis of relevant factors, with
10 respect to—

11 “(i) how well the contractor meets
12 such minimum standards;

13 “(ii) the amount that the contractor
14 will charge the Secretary for administering
15 the benefits under the contract;

16 “(iii) the performance standards es-
17 tablished under subsection (c)(2) and per-
18 formance requirements for which the ad-
19 ministrative fee of the entity will be subject
20 to risk pursuant to subsection (c)(4)(A)(ii);

21 “(iv) the proposed negotiated prices of
22 covered outpatient medicines and annual
23 increases in such prices;

1 “(v) factors relating to benefits, qual-
2 ity and performance, beneficiary cost-shar-
3 ing, and consumer satisfaction;

4 “(vi) past performance and prior ex-
5 perience of the contractor in administering
6 a prescription medicine benefit program;

7 “(vii) effectiveness of the contractor
8 in containing costs through pricing incen-
9 tives and utilization management; and

10 “(viii) such other factors as the Sec-
11 retary deems necessary to evaluate the
12 merits of each bid.

13 “(C) EXCEPTION TO CONFLICT OF INTER-
14 EST RULES.—In awarding contracts with phar-
15 macy contractors under this part, the Secretary
16 may waive conflict of interest laws generally ap-
17 plicable to Federal acquisitions (subject to such
18 safeguards as the Secretary may find necessary
19 to impose) in circumstances where the Sec-
20 retary finds that such waiver—

21 “(i) is not inconsistent with the—

22 “(I) purposes of the programs
23 under this part; or

24 “(II) best interests of bene-
25 ficiaries enrolled under this part; and

1 “(ii) permits a sufficient level of com-
2 petition for such contracts, promotes effi-
3 ciency of benefits administration, or other-
4 wise serves the objectives of the program
5 under this part.

6 “(D) NO ADMINISTRATIVE OR JUDICIAL
7 REVIEW.—The determination of the Secretary
8 to award or not award a contract to a phar-
9 macy contractor under this part shall not be
10 subject to administrative or judicial review.

11 “(9) ACCESS TO BENEFITS IN CERTAIN
12 AREAS.—

13 “(A) AREAS NOT COVERED BY CON-
14 TRACTS.—The Secretary shall develop proce-
15 dures for the provision of covered outpatient
16 prescription medicines under this part to each
17 eligible beneficiary enrolled under this part that
18 resides in an area that is not covered by any
19 contract under this part.

20 “(B) BENEFICIARIES RESIDING IN DIF-
21 FERENT LOCATIONS.—The Secretary shall de-
22 velop procedures to ensure that each eligible
23 beneficiary enrolled under this part that resides
24 in different areas in a year is provided the ben-
25 efits under this part throughout the entire year.

1 “(b) QUALITY, FINANCIAL, AND OTHER STANDARDS
2 AND PROGRAMS.—In consultation with appropriate phar-
3 macy contractors, pharmacists, and health care profes-
4 sionals with expertise in prescribing, dispensing, and the
5 appropriate use of prescription medicines, the Secretary
6 shall establish standards and programs for the administra-
7 tion of this part to ensure appropriate prescribing, dis-
8 pensing, and utilization of outpatient medicines under this
9 part, to avoid adverse medicine reactions, and to contin-
10 ually reduce errors in the delivery of medically appropriate
11 covered benefits. The Secretary shall not award a contract
12 to a pharmacy contractor under this part unless the Sec-
13 retary finds that the contractor agrees to comply with
14 such standards and programs and other terms and condi-
15 tions as the Secretary shall specify. The standards and
16 programs under this subsection shall be applied to any ad-
17 ministrative agreements described in subsection (a) the
18 Secretary enters into. Such standards and programs shall
19 include the following:

20 “(1) ACCESS.—

21 “(A) IN GENERAL.—The pharmacy con-
22 tractor shall ensure that covered outpatient pre-
23 scription medicines are accessible and conven-
24 ient to eligible beneficiaries enrolled under this
25 part for whom benefits are administered by the

1 pharmacy contractor, including by offering the
2 services 24 hours a day and 7 days a week for
3 emergencies.

4 “(B) ON-LINE REVIEW.—The pharmacy
5 contractor shall provide for on-line prospective
6 review available 24 hours a day and 7 days a
7 week in order to evaluate each prescription for
8 medicine therapy problems due to duplication,
9 interaction, or incorrect dosage or duration of
10 therapy.

11 “(C) GUARANTEED ACCESS TO MEDICINES
12 IN RURAL AND HARD-TO-SERVE AREAS.—The
13 Secretary shall ensure that all beneficiaries
14 have guaranteed access to the full range of
15 pharmaceuticals under this part, and shall give
16 special attention to access, pharmacist coun-
17 seling, and delivery in rural and hard-to-serve
18 areas, including through the use of incentives
19 such as bonus payments to retail pharmacists
20 in rural areas and extra payments to the phar-
21 macy contractor for the cost of rapid delivery of
22 pharmaceuticals and any other actions nec-
23 essary.

24 “(D) PREFERRED PHARMACY NET-
25 WORKS.—

1 “(i) IN GENERAL.—If a pharmacy
2 contractor uses a preferred pharmacy net-
3 work to deliver benefits under this part,
4 such network shall meet minimum access
5 standards established by the Secretary.

6 “(ii) STANDARDS.—In establishing
7 standards under clause (i), the Secretary
8 shall take into account reasonable dis-
9 tances to pharmacy services in both urban
10 and rural areas.

11 “(E) ADHERENCE TO NEGOTIATED
12 PRICES.—The pharmacy contractor shall have
13 in place procedures to assure compliance of
14 pharmacies with the requirements of subsection
15 (d)(3)(C) (relating to adherence to negotiated
16 prices).

17 “(F) CONTINUITY OF CARE.—

18 “(i) IN GENERAL.—The pharmacy
19 contractor shall ensure that, in the case of
20 an eligible beneficiary who loses coverage
21 under this part with such entity under cir-
22 cumstances that would permit a special
23 election period (as established by the Sec-
24 retary under section 1859C(b)(3)), the
25 contractor will continue to provide cov-

1 erage under this part to such beneficiary
 2 until the beneficiary enrolls and receives
 3 such coverage with another pharmacy con-
 4 tractor under this part or, if eligible, with
 5 a Medicare+Choice organization.

6 “(ii) LIMITED PERIOD.—In no event
 7 shall a pharmacy contractor be required to
 8 provide the extended coverage required
 9 under clause (i) beyond the date which is
 10 30 days after the coverage with such con-
 11 tractor would have terminated but for this
 12 subparagraph.

13 “(2) ENROLLEE GUIDELINES.—The pharmacy
 14 contractor shall, consistent with State law, apply
 15 guidelines for counseling enrollees regarding—

16 “(A) the proper use of covered outpatient
 17 prescription medicine; and

18 “(B) interactions and contra-indications.

19 “(3) EDUCATION.—The pharmacy contractor
 20 shall apply methods to identify and educate pro-
 21 viders, pharmacists, and enrollees regarding—

22 “(A) instances or patterns concerning the
 23 unnecessary or inappropriate prescribing or dis-
 24 pensing of covered outpatient prescription medi-
 25 cines;

1 “(B) instances or patterns of substandard
2 care;

3 “(C) potential adverse reactions to covered
4 outpatient prescription medicines;

5 “(D) inappropriate use of antibiotics;

6 “(E) appropriate use of generic products;
7 and

8 “(F) the importance of using covered out-
9 patient prescription medicines in accordance
10 with the instruction of prescribing providers.

11 “(4) COORDINATION.—The pharmacy con-
12 tractor shall coordinate with State prescription med-
13 icine programs, other pharmacy contractors, phar-
14 macies, and other relevant entities as necessary to
15 ensure appropriate coordination of benefits with re-
16 spect to enrolled individuals when such individual is
17 traveling outside the home service area, and under
18 such other circumstances as the Secretary may
19 specify.

20 “(5) COST DATA.—

21 “(A) The pharmacy contractor shall make
22 data on prescription medicine negotiated prices
23 (including data on discounts) available to the
24 Secretary.

1 “(B) The Secretary shall require, either di-
2 rectly or through a pharmacy contractor, that
3 participating pharmacists, physicians, and man-
4 ufacturers—

5 “(i) maintain their prescription medi-
6 cine cost data (including data on dis-
7 counts) in a form and manner specified by
8 the Secretary;

9 “(ii) make such prescription medicine
10 cost data available for review and audit by
11 the Secretary; and

12 “(iii) certify that the prescription
13 medicine cost data are current, accurate,
14 and complete, and reflect all discounts ob-
15 tained by the pharmacist or physician in
16 the purchasing of covered outpatient pre-
17 scription medicines.

18 Discounts referred to in subparagraphs (A) and (B)
19 shall include all volume discounts, manufacturer re-
20 bates, prompt payment discounts, free goods, in-kind
21 services, or any other thing of financial value pro-
22 vided explicitly or implicitly in exchange for the pur-
23 chase of a covered outpatient prescription medicine.

1 “(6) REPORTING.—The pharmacy contractor
2 shall provide the Secretary with periodic reports
3 on—

4 “(A) the contractor’s costs of admin-
5 istering this part;

6 “(B) utilization of benefits under this part;

7 “(C) marketing and advertising expendi-
8 tures related to enrolling and retaining individ-
9 uals under this part; and

10 “(D) grievances and appeals.

11 “(7) RECORDS AND AUDITS.—The pharmacy
12 contractor shall maintain adequate records related to
13 the administration of benefits under this part and
14 afford the Secretary access to such records for au-
15 diting purposes.

16 “(8) APPROVAL OF MARKETING MATERIAL AND
17 APPLICATION FORMS.—The pharmacy contractor
18 shall comply with requirements of section 1851(h)
19 (relating to marketing material and application
20 forms) with respect to this part in the same manner
21 as such requirements apply under part C, except
22 that the provisions of paragraph (4)(A) of such sec-
23 tion shall not apply with respect to discounts or re-
24 bates provided in accordance with this part.

1 “(c) INCENTIVES FOR COST AND UTILIZATION MAN-
2 AGEMENT AND QUALITY IMPROVEMENT.—

3 “(1) IN GENERAL.—The Secretary shall include
4 in a contract awarded under subsection (b) with a
5 pharmacy contractor such incentives for cost and
6 utilization management and quality improvement as
7 the Secretary may deem appropriate. The contract
8 may provide financial or other incentives to encour-
9 age greater savings to the program under this part.

10 “(2) PERFORMANCE STANDARDS.—The Sec-
11 retary shall provide for performance standards
12 (which may include monetary bonuses if the stand-
13 ards are met and penalties if the standards are not
14 met), including standards relating to the time taken
15 to answer member and pharmacy inquiries (written
16 or by telephone), the accuracy of responses, claims
17 processing accuracy, online system availability, ap-
18 peal procedure turnaround time, system availability,
19 the accuracy and timeliness of reports, and level of
20 beneficiary satisfaction.

21 “(3) OTHER INCENTIVES.—Such incentives
22 under this subsection may also include—

23 “(A) financial incentives under which sav-
24 ings derived from the substitution of generic
25 and other preferred multi-source medicines in

1 lieu of nongeneric and nonpreferred medicines
2 are made available to pharmacy contractors,
3 pharmacies, beneficiaries, and the Federal
4 Medicare Prescription Medicine Trust Fund;
5 and

6 “(B) any other incentive that the Secretary
7 deems appropriate and likely to be effective in
8 managing costs or utilization or improving qual-
9 ity that does not reduce the access of bene-
10 ficiaries to medically necessary covered out-
11 patient medicines.

12 “(4) REQUIREMENTS FOR PROCEDURES.—

13 “(A) IN GENERAL.—The Secretary shall
14 establish procedures for making payments to
15 each pharmacy contractor with a contract under
16 this part for the administration of the benefits
17 under this part. The procedures shall provide
18 for the following:

19 “(i) ADMINISTRATIVE PAYMENT.—
20 Payment of administrative fees for such
21 administration.

22 “(ii) RISK REQUIREMENT.—An ad-
23 justment of a percentage (determined
24 under subparagraph (B)) of the adminis-
25 trative fee payments made to a pharmacy

1 contractor to ensure that the contractor, in
2 administering the benefits under this part,
3 pursues performance requirements estab-
4 lished by the Secretary, including the fol-
5 lowing:

6 “(I) QUALITY SERVICE.—The
7 contractor provides eligible bene-
8 ficiaries for whom it administers bene-
9 fits with quality services, as measured
10 by such factors as sustained pharmacy
11 network access, timeliness and accu-
12 racy of service delivery in claims proc-
13 essing and card production, pharmacy
14 and member service support access,
15 and timely action with regard to ap-
16 peals and current beneficiary service
17 surveys.

18 “(II) QUALITY CLINICAL CARE.—
19 The contractor provides such bene-
20 ficiaries with quality clinical care, as
21 measured by such factors as providing
22 notification to such beneficiaries and
23 to providers in order to prevent ad-
24 verse drug reactions and reduce medi-
25 cation errors and specific clinical sug-

1 gestions to improve health and patient
2 and prescriber education as appro-
3 priate.

4 “(III) CONTROL OF MEDICARE
5 COSTS.—The contractor contains costs
6 under this part to the Federal Medi-
7 care Prescription Medicine Trust
8 Fund and enrollees, as measured by
9 generic substitution rates, price dis-
10 counts, and other factors determined
11 appropriate by the Secretary that do
12 not reduce the access of beneficiaries
13 to medically necessary covered out-
14 patient prescription medicines.

15 “(B) PERCENTAGE OF PAYMENT TIED TO
16 RISK.—

17 “(i) IN GENERAL.—Subject to clause
18 (ii), the Secretary shall determine the per-
19 centage of the administrative payments to
20 a pharmacy contractor that will be tied to
21 the performance requirements described in
22 subparagraph (A)(ii).

23 “(ii) LIMITATION ON RISK TO ENSURE
24 PROGRAM STABILITY.—In order to provide
25 for program stability, the Secretary may

1 not establish a percentage to be adjusted
2 under this paragraph at a level that jeop-
3 ardizes the ability of a pharmacy con-
4 tractor to administer the benefits under
5 this part or administer such benefits in a
6 quality manner.

7 “(C) RISK ADJUSTMENT OF PAYMENTS
8 BASED ON ENROLLEES IN PLAN.—To the extent
9 that a pharmacy contractor is at risk under this
10 paragraph, the procedures established under
11 this paragraph may include a methodology for
12 risk adjusting the payments made to such con-
13 tractor based on the differences in actuarial
14 risk of different enrollees being served if the
15 Secretary determines such adjustments to be
16 necessary and appropriate.

17 “(d) AUTHORITY RELATING TO PHARMACY PARTICI-
18 PATION.—

19 “(1) IN GENERAL.—Subject to the succeeding
20 provisions of this subsection, a pharmacy contractor
21 may establish consistent with this part conditions for
22 the participation of pharmacies, including conditions
23 relating to quality (including reduction of medical
24 errors) and technology.

1 “(2) AGREEMENTS WITH PHARMACIES.—Each
2 pharmacy contractor shall enter into a participation
3 agreement with any pharmacy that meets the re-
4 quirements of this subsection and section 1859E to
5 furnish covered outpatient prescription medicines to
6 individuals enrolled under this part.

7 “(3) TERMS OF AGREEMENT.—An agreement
8 under this subsection shall include the following
9 terms and conditions:

10 “(A) APPLICABLE REQUIREMENTS.—The
11 pharmacy shall meet (and throughout the con-
12 tract period continue to meet) all applicable
13 Federal requirements and State and local li-
14 censing requirements.

15 “(B) ACCESS AND QUALITY STANDARDS.—
16 The pharmacy shall comply with such standards
17 as the Secretary (and such a pharmacy con-
18 tractor) shall establish concerning the quality
19 of, and enrolled individuals’ access to, phar-
20 macy services under this part. Such standards
21 shall require the pharmacy—

22 “(i) not to refuse to dispense covered
23 outpatient prescription medicines to any
24 individual enrolled under this part;

1 “(ii) to keep patient records (includ-
2 ing records on expenses) for all covered
3 outpatient prescription medicines dispensed
4 to such enrolled individuals;

5 “(iii) to submit information (in a
6 manner specified by the Secretary to be
7 necessary to administer this part) on all
8 purchases of such medicines dispensed to
9 such enrolled individuals; and

10 “(iv) to comply with periodic audits to
11 assure compliance with the requirements of
12 this part and the accuracy of information
13 submitted.

14 “(C) ADHERENCE TO NEGOTIATED
15 PRICES.—(i) The total charge for each medicine
16 dispensed by the pharmacy to an enrolled indi-
17 vidual under this part, without regard to wheth-
18 er the individual is financially responsible for
19 any or all of such charge, shall not exceed the
20 price negotiated under section 1859A(a) or, if
21 lower, negotiated under subsection (a)(5) (or, if
22 less, the retail price for the medicine involved)
23 with respect to such medicine plus a reasonable
24 dispensing fee determined contractually with
25 the pharmacy contractor.

1 “(ii) The pharmacy does not charge (or
 2 collect from) an enrolled individual an amount
 3 that exceeds the individual’s obligation (as de-
 4 termined in accordance with the provisions of
 5 this part) of the applicable price described in
 6 clause (i).

7 “(D) ADDITIONAL REQUIREMENTS.—The
 8 pharmacy shall meet such additional contract
 9 requirements as the applicable pharmacy con-
 10 tractor specifies under this section.

11 “(4) APPLICABILITY OF FRAUD AND ABUSE
 12 PROVISIONS.—The provisions of section 1128
 13 through 1128C (relating to fraud and abuse) apply
 14 to pharmacies participating in the program under
 15 this part.

16 “ELIGIBILITY; VOLUNTARY ENROLLMENT; COVERAGE

17 “SEC. 1859C. (a) ELIGIBILITY.—Each individual
 18 who is entitled to hospital insurance benefits under part
 19 A or is eligible to be enrolled in the medical insurance pro-
 20 gram under part B is eligible to enroll in accordance with
 21 this section for outpatient prescription medicine benefits
 22 under this part.

23 “(b) VOLUNTARY ENROLLMENT.—

24 “(1) IN GENERAL.—An individual may enroll
 25 under this part only in such manner and form as
 26 may be prescribed by regulations, and only during

1 an enrollment period prescribed in or under this sub-
2 section.

3 “(2) INITIAL ENROLLMENT PERIOD.—

4 “(A) INDIVIDUALS CURRENTLY COV-
5 ERED.—In the case of an individual who satis-
6 fies subsection (a) as of November 1, 2005, the
7 initial general enrollment period shall begin on
8 August 1, 2005, and shall end on March 1,
9 2006.

10 “(B) INDIVIDUAL COVERED IN FUTURE.—

11 In the case of an individual who first satisfies
12 subsection (a) on or after November 1, 2005,
13 the individual’s initial enrollment period shall
14 begin on the first day of the third month before
15 the month in which such individual first satis-
16 fies such paragraph and shall end seven months
17 later. The Secretary shall apply rules similar to
18 the rule described in the second sentence of sec-
19 tion 1837(d).

20 “(3) SPECIAL ENROLLMENT PERIODS (WITHOUT
21 PREMIUM PENALTY).—

22 “(A) EMPLOYER COVERAGE AT TIME OF
23 INITIAL GENERAL ENROLLMENT PERIOD.—In
24 the case of an individual who—

1 “(i) at the time the individual first
2 satisfies subsection (a) is enrolled in a
3 group health plan (including continuation
4 coverage) that provides outpatient pre-
5 scription medicine coverage by reason of
6 the individual’s (or the individual’s
7 spouse’s) current (or, in the case of con-
8 tinuation coverage, former) employment
9 status, and

10 “(ii) has elected not to enroll (or to be
11 deemed enrolled) under this subsection
12 during the individual’s initial enrollment
13 period,

14 there shall be a special enrollment period of 6
15 months beginning with the first month that in-
16 cludes the date of the individual’s (or individ-
17 ual’s spouse’s) retirement from or termination
18 of current employment status with the employer
19 that sponsors the plan, or, in the case of con-
20 tinuation coverage, that includes the date of
21 termination of such coverage, or that includes
22 the date the plan substantially terminates out-
23 patient prescription medicine coverage.

“(B) DROPPING OF RETIREE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who—

“(i) at the time the individual first satisfies subsection (a) is enrolled in a group health plan that provides outpatient prescription medicine coverage other than by reason of the individual’s (or the individual’s spouse’s) current employment; and

“(ii) has elected not to enroll (or to be deemed enrolled) under this subsection during the individual’s initial enrollment period,

there shall be a special enrollment period of 6 months beginning with the first month that includes the date that the plan substantially terminates outpatient prescription medicine coverage and ending 6 months later.

“(C) LOSS OF MEDICARE+CHOICE PRESCRIPTION MEDICINE COVERAGE.—In the case of an individual who is enrolled under part C in a Medicare+Choice plan that provides prescription medicine benefits, if such enrollment is terminated because of the termination or reduction in service area of the plan, there shall be a spe-

1 cial enrollment period of 6 months beginning
 2 with the first month that includes the date that
 3 such plan is terminated or such reduction oc-
 4 curs and ending 6 months later.

5 “(D) LOSS OF MEDICAID PRESCRIPTION
 6 MEDICINE COVERAGE.—In the case of an indi-
 7 vidual who—

8 “(i) satisfies subsection (a);

9 “(ii) loses eligibility for benefits (that
 10 include benefits for prescription medicine)
 11 under a State plan after having been en-
 12 rolled (or determined to be eligible) for
 13 such benefits under such plan; and

14 “(iii) is not otherwise enrolled under
 15 this subsection at the time of such loss of
 16 eligibility,

17 there shall be a special enrollment period speci-
 18 fied by the Secretary of not less than 6 months
 19 beginning with the first month that includes the
 20 date that the individual loses such eligibility.

21 “(4) LATE ENROLLMENT WITH PREMIUM PEN-
 22 ALTY.—The Secretary shall permit an individual
 23 who satisfies subsection (a) to enroll other than dur-
 24 ing the initial enrollment period under paragraph (2)
 25 or a special enrollment period under paragraph (3).

1 But, in the case of such an enrollment, the amount
2 of the monthly premium of the individual is subject
3 to an increase under section 1859C(e)(1).

4 “(5) INFORMATION.—

5 “(A) IN GENERAL.—The Secretary shall
6 broadly distribute information to individuals
7 who satisfy subsection (a) on the benefits pro-
8 vided under this part. The Secretary shall peri-
9 odically make available information on the cost
10 differentials to enrollees for the use of generic
11 medicines and other medicines.

12 “(B) TOLL-FREE HOTLINE.—The Sec-
13 retary shall maintain a toll-free telephone hot-
14 line (which may be a hotline already used by
15 the Secretary under this title) for purposes of
16 providing assistance to beneficiaries in the pro-
17 gram under this part, including responding to
18 questions concerning coverage, enrollment, ben-
19 efits, grievances and appeals procedures, and
20 other aspects of such program.

21 “(6) ENROLLEE DEFINED.—For purposes of
22 this part, the term ‘enrollee’ means an individual en-
23 rolled for benefits under this part.

24 “(c) COVERAGE PERIOD.—

1 “(1) IN GENERAL.—The period during which
 2 an individual is entitled to benefits under this part
 3 (in this subsection referred to as the individual’s
 4 ‘coverage period’) shall begin on such a date as the
 5 Secretary shall establish consistent with the type of
 6 coverage rules described in subsections (a) and (e)
 7 of section 1838, except that in no case shall a cov-
 8 erage period begin before January 1, 2006. No pay-
 9 ments may be made under this part with respect to
 10 the expenses of an individual unless such expenses
 11 were incurred by such individual during a period
 12 which, with respect to the individual, is a coverage
 13 period.

14 “(2) TERMINATION.—The Secretary shall pro-
 15 vide for the application of provisions under this sub-
 16 section similar to the provisions in section 1838(b).

17 “(d) PROVISION OF BENEFITS TO
 18 MEDICARE+CHOICE ENROLLEES.—In the case of an indi-
 19 vidual who is enrolled under this part and is enrolled in
 20 a Medicare+Choice plan under part C, the individual shall
 21 be provided the benefits under this part through such plan
 22 and not through payment under this part.

23 “(e) LATE ENROLLMENT PENALTIES; PAYMENT OF
 24 PREMIUMS.—

25 “(1) LATE ENROLLMENT PENALTY.—

1 “(A) IN GENERAL.—In the case of a late
2 enrollment described in subsection (b)(4), sub-
3 ject to the succeeding provisions of this para-
4 graph, the Secretary shall establish procedures
5 for increasing the amount of the monthly pre-
6 mium under this part applicable to such en-
7 rollee by an amount that the Secretary deter-
8 mines is actuarially sound for each such period.

9 “(B) PERIODS TAKEN INTO ACCOUNT.—
10 For purposes of calculating any 12-month pe-
11 riod under subparagraph (A), there shall be
12 taken into account months of lapsed coverage in
13 a manner comparable to that applicable under
14 the second sentence of section 1839(b).

15 “(C) PERIODS NOT TAKEN INTO AC-
16 COUNT.—

17 “(i) IN GENERAL.—For purposes of
18 calculating any 12-month period under
19 subparagraph (A), subject to clause (ii),
20 there shall not be taken into account
21 months for which the enrollee can dem-
22 onstrate that the enrollee was covered
23 under a group health plan that provides
24 coverage of the cost of prescription medi-
25 cines whose actuarial value (as defined by

1 the Secretary) to the enrollee equals or ex-
2 ceeds the actuarial value of the benefits
3 provided to an individual enrolled in the
4 outpatient prescription medicine benefit
5 program under this part.

6 “(ii) APPLICATION.—This subpara-
7 graph shall only apply with respect to a
8 coverage period the enrollment for which
9 occurs before the end of the 60-day period
10 that begins on the first day of the month
11 which includes the date on which the plan
12 terminates or reduces its service area (in a
13 manner that results in termination of en-
14 rollment), ceases to provide, or reduces the
15 value of the prescription medicine coverage
16 under such plan to below the value of the
17 coverage provided under the program
18 under this part.

19 “(2) INCORPORATION OF PREMIUM PAYMENT
20 AND GOVERNMENT CONTRIBUTIONS PROVISIONS.—

21 The provisions of sections 1840 and 1844(a)(1) shall
22 apply to enrollees under this part in the same man-
23 ner as they apply to individuals 65 years of age or
24 older enrolled under part B. For purposes of this
25 subsection, any reference in a section referred to in

1 a previous subsection to the Federal Supplementary
 2 Medical Insurance Trust Fund is deemed a reference
 3 to the Federal Medicare Prescription Medicine Trust
 4 Fund.

5 “(f) ELECTION OF PHARMACY CONTRACTOR TO AD-
 6 MINISTER BENEFITS.—The Secretary shall establish a
 7 process whereby each individual enrolled under this part
 8 and residing in a region may elect the pharmacy con-
 9 tractor that will administer the benefits under this part
 10 with respect to the individual. Such process shall permit
 11 the individual to make an initial election and to change
 12 such an election on at least an annual basis and under
 13 such other circumstances as the Secretary shall specify.

14 “PROVISION OF, AND ENTITLEMENT TO, BENEFITS

15 “SEC. 1859D. (a) BENEFITS.—Subject to the suc-
 16 ceeding provisions of this section, the benefits provided to
 17 an enrollee by the program under this part shall consist
 18 of the following:

19 “(1) COVERED OUTPATIENT PRESCRIPTION
 20 MEDICINE BENEFITS.—Entitlement to have payment
 21 made on the individual’s behalf for covered out-
 22 patient prescription medicines.

23 “(2) LIMITATION ON COST-SHARING FOR PART
 24 B OUTPATIENT PRESCRIPTION MEDICINES.—

25 “(A) IN GENERAL.—Once an enrollee has
 26 incurred aggregate countable cost-sharing (as

defined in subparagraph (B)) equal to the stop-loss limit specified in subsection (c)(4) for expenses in a year, entitlement to the elimination of cost-sharing otherwise applicable under part B for additional expenses incurred in the year for outpatient prescription medicines or biologicals for which payment is made under part B.

“(B) COUNTABLE COST-SHARING DEFINED.—For purposes of this part, the term ‘countable cost-sharing’ means—

“(i) out-of-pocket expenses for outpatient prescription medicines with respect to which benefits are payable under part B, and

“(ii) cost-sharing under subsections (c)(3)(B) and (c)(3)(C)(i).

“(b) COVERED OUTPATIENT PRESCRIPTION MEDICINE DEFINED.—

“(1) IN GENERAL.—Except as provided in paragraph (2), for purposes of this part the term ‘covered outpatient prescription medicine’ means any of the following products:

“(A) A medicine which may be dispensed only upon prescription, and—

1 “(i) which is approved for safety and
2 effectiveness as a prescription medicine
3 under section 505 of the Federal Food,
4 Drug, and Cosmetic Act;

5 “(ii)(I) which was commercially used
6 or sold in the United States before the
7 date of enactment of the Drug Amend-
8 ments of 1962 or which is identical, simi-
9 lar, or related (within the meaning of sec-
10 tion 310.6(b)(1) of title 21 of the Code of
11 Federal Regulations) to such a medicine,
12 and

13 (II) which has not been the subject of
14 a final determination by the Secretary that
15 it is a ‘new drug’ (within the meaning of
16 section 201(p) of the Federal Food, Drug,
17 and Cosmetic Act) or an action brought by
18 the Secretary under section 301, 302(a),
19 or 304(a) of such Act to enforce section
20 502(f) or 505(a) of such Act; or

21 “(iii)(I) which is described in section
22 107(c)(3) of the Drug Amendments of
23 1962 and for which the Secretary has de-
24 termined there is a compelling justification
25 for its medical need, or is identical, simi-

1 lar, or related (within the meaning of sec-
2 tion 310.6(b)(1) of title 21 of the Code of
3 Federal Regulations) to such a medicine,
4 and

5 (II) for which the Secretary has not
6 issued a notice of an opportunity for a
7 hearing under section 505(e) of the Fed-
8 eral Food, Drug, and Cosmetic Act on a
9 proposed order of the Secretary to with-
10 draw approval of an application for such
11 medicine under such section because the
12 Secretary has determined that the medi-
13 cine is less than effective for all conditions
14 of use prescribed, recommended, or sug-
15 gested in its labeling.

16 “(B) A biological product which—

17 “(i) may only be dispensed upon pre-
18 scription;

19 “(ii) is licensed under section 351 of
20 the Public Health Service Act; and

21 “(iii) is produced at an establishment
22 licensed under such section to produce
23 such product.

24 “(C) Insulin approved under appropriate
25 Federal law, and needles, syringes, and dispos-

1 able pumps for the administration of such insu-
2 lin.

3 “(D) A prescribed medicine or biological
4 product that would meet the requirements of
5 subparagraph (A) or (B) but that is available
6 over-the-counter in addition to being available
7 upon prescription, but only if the particular
8 dosage form or strength prescribed and re-
9 quired for the individual is not available over-
10 the-counter.

11 “(E) Smoking cessation agents (as speci-
12 fied by the Secretary).

13 “(2) EXCLUSION.—The term ‘covered out-
14 patient prescription medicine’ does not include—

15 “(A) medicines or classes of medicines, or
16 their medical uses, which may be excluded from
17 coverage or otherwise restricted under section
18 1927(d)(2), other than subparagraph (E) there-
19 of (relating to smoking cessation agents), as the
20 Secretary may specify and does not include
21 such other medicines, classes, and uses as the
22 Secretary may specify consistent with the goals
23 of providing quality care and containing costs
24 under this part;

1 “(B) except as provided in paragraphs
 2 (1)(D) and (1)(E), any product which may be
 3 distributed to individuals without a prescrip-
 4 tion;

5 “(C) any product when furnished as part
 6 of, or as incident to, a diagnostic service or any
 7 other item or service for which payment may be
 8 made under this title; or

9 “(D) any product that is covered under
 10 part B of this title.

11 “(c) PAYMENT OF BENEFITS.—

12 “(1) COVERED OUTPATIENT PRESCRIPTION
 13 MEDICINES.—There shall be paid from the Federal
 14 Medicare Prescription Medicine Trust Fund, in the
 15 case of each enrollee who incurs expenses for medi-
 16 cines with respect to which benefits are payable
 17 under this part under subsection (a)(1), amounts
 18 equal to the sum of—

19 “(A) the price for which the medicine is
 20 made available under this part (consistent with
 21 sections 1859A and 1859B), reduced by any
 22 applicable cost-sharing under paragraphs (2)
 23 and (3); and

24 “(B) a reasonable dispensing fee.

1 The price under subparagraph (A) shall in no case
2 exceed the retail price for the medicine involved.

3 “(2) DEDUCTIBLE.—The amount of payment
4 under paragraph (1) for expenses incurred in a year,
5 beginning with 2006, shall be reduced by an annual
6 deductible equal to the amount specified in section
7 1859(2) (subject to adjustment under paragraph
8 (8)). Only expenses for countable cost-sharing (as
9 defined in subsection (a)(2)(B)) shall be taken into
10 account in applying this paragraph.

11 “(3) COINSURANCE.—

12 “(A) IN GENERAL.—The amount of pay-
13 ment under paragraph (1) for expenses in-
14 curred in a year shall be further reduced (sub-
15 ject to the stop-loss limit under paragraph (4))
16 by coinsurance as provided under this para-
17 graph.

18 “(B) PREFERRED MEDICINES.—The coin-
19 surance under this paragraph in the case of a
20 preferred medicine (including a medicine treat-
21 ed as a preferred medicine under paragraph
22 (5)), is equal to 20 percent of the price applica-
23 ble under paragraph (1)(A) (or such lower per-
24 centage as may be provided for under section
25 1859E(a)(1)(A)(ii)). In this part, the term ‘pre-

ferred medicine’ means, with respect to medicines classified within a therapeutic class, those medicines which have been designated as a preferred medicine by the Secretary or the pharmacy contractor involved with respect to that class and (in the case of a nongeneric medicine) with respect to which a contract has been negotiated under this part.

“(C) NONPREFERRED MEDICINES.—The coinsurance under this paragraph in the case of a nonpreferred medicine that is not treated as a preferred medicine under paragraph (5) is equal to the sum of—

“(i) 20 percent of the price for lowest price preferred medicine that is within the same therapeutic class; and

“(ii) the amount by which—

“(I) the price at which the nonpreferred medicine is made available to the enrollee; exceeds

“(II) the price of such lowest price preferred medicine.

“(4) NO COINSURANCE ONCE OUT-OF-POCKET EXPENDITURES EQUAL STOP-LOSS LIMIT.—Once an enrollee has incurred aggregate countable cost-shar-

ing under paragraph (3) (including cost-sharing under part B attributable to outpatient prescription drugs or biologicals) equal to the amount specified in section 1859(4) (subject to adjustment under paragraph (8)) for expenses in a year—

“(A) there shall be no coinsurance under paragraph (3) for additional expenses incurred in the year involved; and

“(B) there shall be no coinsurance under part B for additional expenses incurred in the year involved for outpatient prescription drugs and biologicals.

“(5) APPEALS RIGHTS RELATING TO COVERAGE OF NONPREFERRED MEDICINES.—

“(A) PROCEDURES REGARDING THE DETERMINATION OF MEDICINES THAT ARE MEDICALLY NECESSARY.—Each pharmacy contractor shall have in place procedures on a case-by-case basis to treat a nonpreferred medicine as a preferred medicine under this part if the preferred medicine is determined to be not as effective for the enrollee or to have significant adverse effect on the enrollee. Such procedures shall require that such determinations are based on profes-

1 sional medical judgment, the medical condition
2 of the enrollee, and other medical evidence.

3 “(B) PROCEDURES REGARDING DENIALS
4 OF CARE.—Such contractor shall have in place
5 procedures to ensure—

6 “(i) a timely internal review for reso-
7 lution of denials of coverage (in whole or
8 in part and including those regarding the
9 coverage of nonpreferred medicines) in ac-
10 cordance with the medical exigencies of the
11 case and a timely resolution of complaints,
12 by enrollees in the plan, or by providers,
13 pharmacists, and other individuals acting
14 on behalf of each such enrollee (with the
15 enrollee’s consent) in accordance with re-
16 quirements (as established by the Sec-
17 retary) that are comparable to such re-
18 quirements for Medicare+Choice organiza-
19 tions under part C;

20 “(ii) that the entity complies in a
21 timely manner with requirements estab-
22 lished by the Secretary that (I) provide for
23 an external review by an independent enti-
24 ty selected by the Secretary of denials of
25 coverage described in clause (i) not re-

solved in the favor of the beneficiary (or other complainant) under the process described in such clause and (II) are comparable to the external review requirements established for Medicare+Choice organizations under part C; and

“(iii) that enrollees are provided with information regarding the appeals procedures under this part at the time of enrollment with a pharmacy contractor under this part and upon request thereafter.

“(6) TRANSFER OF FUNDS TO COVER COSTS OF PART B PRESCRIPTION MEDICINE CATASTROPHIC BENEFIT.—With respect to benefits described in subsection (a)(2), there shall be transferred from the Federal Medicare Prescription Medicine Trust Fund to the Federal Supplementary Medical Insurance Trust Fund amounts equivalent to the elimination of cost-sharing described in such subsection.

“(7) PERMITTING APPLICATION UNDER PART B OF NEGOTIATED PRICES.—For purposes of making payment under part B for medicines that would be covered outpatient prescription medicines but for the exclusion under subparagraph (B) or (C) of subsection (b)(2), the Secretary may elect to apply the

1 payment basis used for payment of covered out-
 2 patient prescription medicines under this part in-
 3 stead of the payment basis otherwise used under
 4 such part, if it results in a lower cost to the pro-
 5 gram.

6 “(8) INFLATION ADJUSTMENT.—

7 “(A) IN GENERAL.—With respect to ex-
 8 penses incurred in a year after 2006—

9 “(i) the deductible under paragraph
 10 (2) is equal to the deductible determined
 11 under such paragraph (or this subpara-
 12 graph) for the previous year increased by
 13 the percentage increase in per capita pro-
 14 gram expenditures (as estimated in ad-
 15 vance for the year involved under subpara-
 16 graph (B)); and

17 “(ii) the stop-loss limit under para-
 18 graph (3) is equal to the stop-loss limit de-
 19 termined under such paragraph (or this
 20 subparagraph) for the previous year in-
 21 creased by such percentage increase.

22 The Secretary shall adjust such percentage in-
 23 crease in subsequent years to take into account
 24 misestimations made of the per capita program
 25 expenditures under clauses (i) and (ii) in pre-

1 vious years. Any increase under this subpara-
 2 graph that is not a multiple of \$10 shall be
 3 rounded to the nearest multiple of \$10.

4 “(B) ESTIMATION OF INCREASE IN PER
 5 CAPITA PROGRAM EXPENDITURES.—The Sec-
 6 retary shall before the beginning of each year
 7 (beginning with 2007) estimate the percentage
 8 increase in average per capita aggregate ex-
 9 penditures from the Federal Medicare Prescrip-
 10 tion Medicine Trust Fund for the year involved
 11 compared to the previous year.

12 “(C) RECONCILIATION.—The Secretary
 13 shall also compute (beginning with 2008) the
 14 actual percentage increase in such aggregate
 15 expenditures in order to provide for reconcili-
 16 ation of deductibles, stop-loss limits, and pre-
 17 miums under the second sentence of subpara-
 18 graph (A) and under section 1859D(d)(2).

19 “(d) AMOUNT OF PREMIUMS.—

20 “(1) MONTHLY PREMIUM RATE IN 2006.—The
 21 monthly premium rate in 2006 for prescription med-
 22 icine benefits under this part is the amount specified
 23 in section 1859(1).

24 “(2) INFLATION ADJUSTMENT FOR SUBSE-
 25 QUENT YEARS.—The monthly premium rate for a

1 year after 2006 for prescription medicine benefits
 2 under this part is equal to the monthly premium
 3 rate for the previous year under this subsection in-
 4 creased by the percentage increase in per capita pro-
 5 gram expenditures (as estimated in advance for the
 6 year involved under subsection (c)(8)(B)). The Sec-
 7 retary shall adjust such percentage in subsequent
 8 years to take into account misestimations made of
 9 the per capita program expenditures under the pre-
 10 vious sentence in previous years. Any increase under
 11 this paragraph that is not a multiple of \$1 shall be
 12 rounded to the nearest multiple of \$1.

13 “ADMINISTRATION; QUALITY ASSURANCE

14 “SEC. 1859E. (a) RULES RELATING TO PROVISION
 15 OF BENEFITS.—

16 “(1) PROVISION OF BENEFITS.—

17 “(A) IN GENERAL.—In providing benefits
 18 under this part, the Secretary (directly or
 19 through the contracts with pharmacy contrac-
 20 tors) shall employ mechanisms to provide bene-
 21 fits appropriately and efficiently, and those
 22 mechanisms may include—

23 “(i) the use of—

24 “(I) price negotiations (con-
 25 sistent with subsection (b));

1 “(II) reduced coinsurance (below
2 20 percent) to encourage the utiliza-
3 tion of appropriate preferred medi-
4 cines; and

5 “(III) methods to reduce medica-
6 tion errors and encourage appropriate
7 use of medications; and

8 “(ii) permitting pharmacy contractors,
9 as approved by the Secretary, to make ex-
10 ceptions to section 1859D(c)(3)(C) (relat-
11 ing to cost-sharing for non-preferred medi-
12 cines) to secure best prices for enrollees so
13 long as the payment amount under section
14 1859D(c)(1) does not equal zero.

15 “(B) CONSTRUCTION.—Nothing in this
16 subsection shall be construed to prevent the
17 Secretary (directly or through the contracts
18 with pharmacy contractors) from using incen-
19 tives to encourage enrollees to select generic or
20 other cost-effective medicines, so long as—

21 “(i) such incentives are designed not
22 to result in any increase in the aggregate
23 expenditures under the Federal Medicare
24 Prescription Medicine Trust Fund; and

1 “(ii) a beneficiary’s coinsurance shall
2 be no greater than 20 percent in the case
3 of a preferred medicine (including a non-
4 preferred medicine treated as a preferred
5 medicine under section 1859D(c)(5)).

6 “(2) CONSTRUCTION.—Nothing in this part
7 shall preclude the Secretary or a pharmacy con-
8 tractor from—

9 “(A) educating prescribing providers, phar-
10 macists, and enrollees about medical and cost
11 benefits of preferred medicines;

12 “(B) requesting prescribing providers to
13 consider a preferred medicine prior to dis-
14 pensing of a nonpreferred medicine, as long as
15 such request does not unduly delay the provi-
16 sion of the medicine;

17 “(C) using mechanisms to encourage en-
18 rollees under this part to select cost-effective
19 medicines or less costly means of receiving or
20 administering medicines, including the use of
21 therapeutic interchange programs, disease man-
22 agement programs, and notification to the bene-
23 ficiary that a more affordable generic medicine
24 equivalent was not selected by the prescribing

1 provider and a statement of the lost cost sav-
 2 ings to the beneficiary;

3 “(D) using price negotiations to achieve re-
 4 duced prices on covered outpatient prescription
 5 medicines, including new medicines, medicines
 6 for which there are few therapeutic alternatives,
 7 and medicines of particular clinical importance
 8 to individuals enrolled under this part; and

9 “(E) utilizing information on medicine
 10 prices of OECD countries and of other payors
 11 in the United States in the negotiation of prices
 12 under this part.

13 “(b) PRICE NEGOTIATIONS PROCESS.—

14 “(1) REQUIREMENTS WITH RESPECT TO PRE-
 15 FERRED MEDICINES.—Negotiations of contracts with
 16 manufacturers with respect to covered outpatient
 17 prescription medicines under this part shall be con-
 18 ducted in a manner so that—

19 “(A) there is at least a contract for a med-
 20 icine within each therapeutic class (as defined
 21 by the Secretary in consultation with such
 22 Medicare Prescription Medicine Advisory Com-
 23 mittee);

24 “(B) if there is more than 1 medicine
 25 available in a therapeutic class, there are con-

1 tracts for at least 2 medicines within such class
2 unless determined clinically inappropriate in ac-
3 cordance with standards established by the Sec-
4 retary; and

5 “(C) if there are more than 2 medicines
6 available in a therapeutic class, there is a con-
7 tract for at least 2 medicines within such class
8 and a contract for generic medicine substitute
9 if available unless determined clinically inappro-
10 prium in accordance with standards established
11 by the Secretary.

12 “(2) ESTABLISHMENT OF THERAPEUTIC CLASS-
13 ES.—The Secretary, in consultation with the Medi-
14 care Prescription Medicine Advisory Committee (es-
15 tablished under section 1859H), shall establish for
16 purposes of this part therapeutic classes and assign
17 to such classes covered outpatient prescription medi-
18 cines.

19 “(3) DISCLOSURE CONCERNING PREFERRED
20 MEDICINES.—The Secretary shall provide, through
21 pharmacy contractors or otherwise, for—

22 “(A) disclosure to current and prospective
23 enrollees and to participating providers and
24 pharmacies in each service area a list of the
25 preferred medicines and differences in applica-

1 ble cost-sharing between such medicines and
2 nonpreferred medicines; and

3 “(B) advance disclosure to current enroll-
4 ees and to participating providers and phar-
5 macies in each service area of changes to any
6 such list of preferred medicines and differences
7 in applicable cost-sharing.

8 “(4) NO REVIEW.—The Secretary’s establish-
9 ment of therapeutic classes and the assignment of
10 medicines to such classes and the Secretary’s deter-
11 mination of what is a breakthrough medicine are not
12 subject to administrative or judicial review.

13 “(c) CONFIDENTIALITY.—The Secretary shall ensure
14 that the confidentiality of individually identifiable health
15 information relating to the provision of benefits under this
16 part is protected, consistent with the standards for the
17 privacy of such information promulgated by the Secretary
18 under the Health Insurance Portability and Accountability
19 Act of 1996, or any subsequent comprehensive and more
20 protective set of confidentiality standards enacted into law
21 or promulgated by the Secretary. Nothing in this sub-
22 section shall be construed as preventing the coordination
23 of data with a State prescription medicine program so long
24 as such program has in place confidentiality standards

1 that are equal to or exceed the standards used by the Sec-
 2 retary.

3 “(d) FRAUD AND ABUSE SAFEGUARDS.—The Sec-
 4 retary, through the Office of the Inspector General, is au-
 5 thorized and directed to issue regulations establishing ap-
 6 propriate safeguards to prevent fraud and abuse under
 7 this part. Such safeguards, at a minimum, should include
 8 compliance programs, certification data, audits, and rec-
 9 ordkeeping practices. In developing such regulations, the
 10 Secretary shall consult with the Attorney General and
 11 other law enforcement and regulatory agencies.

12 “FEDERAL MEDICARE PRESCRIPTION MEDICINE TRUST
 13 FUND

14 “SEC. 1859F. (a) ESTABLISHMENT.—There is here-
 15 by created on the books of the Treasury of the United
 16 States a trust fund to be known as the ‘Federal Medicare
 17 Prescription Medicine Trust Fund’ (in this section re-
 18 ferred to as the ‘Trust Fund’). The Trust Fund shall con-
 19 sist of such gifts and bequests as may be made as provided
 20 in section 201(i)(1), and such amounts as may be depos-
 21 ited in, or appropriated to, such fund as provided in this
 22 part.

23 “(b) APPLICATION OF SMI TRUST FUND PROVI-
 24 SIONS.—The provisions of subsections (b) through (i) of
 25 section 1841 shall apply to this part and the Trust Fund
 26 in the same manner as they apply to part B and the Fed-

1 eral Supplementary Medical Insurance Trust Fund, re-
 2 spectively.

3 “COMPENSATION FOR EMPLOYERS COVERING RETIREE
 4 MEDICINE COSTS

5 “SEC. 1859G. (a) IN GENERAL.—In the case of an
 6 individual who is eligible to be enrolled under this part
 7 and is a participant or beneficiary under a group health
 8 plan that provides outpatient prescription medicine cov-
 9 erage to retirees the actuarial value of which is not less
 10 than the actuarial value of the coverage provided under
 11 this part, the Secretary shall make payments to such plan
 12 subject to the provisions of this section. Such payments
 13 shall be treated as payments under this part for purposes
 14 of sections 1859F and 1859C(e)(2). In applying the pre-
 15 vious sentence with respect to section 1859C(e)(2), the
 16 amount of the Government contribution referred to in sec-
 17 tion 1844(a)(1)(A) is deemed to be equal to the aggregate
 18 amount of the payments made under this section.

19 “(b) REQUIREMENTS.—To receive payment under
 20 this section, a group health plan shall comply with the fol-
 21 lowing requirements:

22 “(1) COMPLIANCE WITH REQUIREMENTS.—The
 23 group health plan shall comply with the require-
 24 ments of this Act and other reasonable, necessary,
 25 and related requirements that are needed to admin-
 26 ister this section, as determined by the Secretary.

1 “(2) ANNUAL ASSURANCES AND NOTICE BE-
2 FORE TERMINATION.—The sponsor of the plan
3 shall—

4 “(A) annually attest, and provide such as-
5 surances as the Secretary may require, that the
6 coverage offered under the group health plan
7 meets the requirements of this section and will
8 continue to meet such requirements for the du-
9 ration of the sponsor’s participation in the pro-
10 gram under this section; and

11 “(B) guarantee that it will give notice to
12 the Secretary and covered enrollees—

13 “(i) at least 120 days before termi-
14 nating its plan, and

15 “(ii) immediately upon determining
16 that the actuarial value of the prescription
17 medicine benefit under the plan falls below
18 the actuarial value required under sub-
19 section (a).

20 “(3) BENEFICIARY INFORMATION.—The spon-
21 sor of the plan shall report to the Secretary, for
22 each calendar quarter for which it seeks a payment
23 under this section, the names and social security
24 numbers of all enrollees described in subsection (a)
25 covered under such plan during such quarter and

1 the dates (if less than the full quarter) during which
2 each such individual was covered.

3 “(4) AUDITS.—The sponsor or plan seeking
4 payment under this section shall agree to maintain,
5 and to afford the Secretary access to, such records
6 as the Secretary may require for purposes of audits
7 and other oversight activities necessary to ensure the
8 adequacy of prescription medicine coverage, the ac-
9 curacy of payments made, and such other matters as
10 may be appropriate.

11 “(c) PAYMENT.—

12 “(1) IN GENERAL.—The sponsor of a group
13 health plan that meets the requirements of sub-
14 section (b) with respect to a quarter in a calendar
15 year shall be entitled to have payment made on a
16 quarterly basis of the amount specified in paragraph
17 (2) for each individual described in subsection (a)
18 who during the quarter is covered under the plan
19 and was not enrolled in the insurance program
20 under this part.

21 “(2) AMOUNT OF PAYMENT.—

22 “(A) IN GENERAL.—The amount of the
23 payment for a quarter shall approximate, for
24 each such covered individual, $\frac{2}{3}$ of the sum of
25 the monthly Government contribution amounts

1 (computed under subparagraph (B)) for each of
 2 the 3 months in the quarter.

3 “(B) COMPUTATION OF MONTHLY GOV-
 4 ERNMENT CONTRIBUTION AMOUNT.—For pur-
 5 poses of subparagraph (A), the monthly Gov-
 6 ernment contribution amount for a month in a
 7 year is equal to the amount by which—

8 “(i) $\frac{1}{12}$ of the average per capita ag-
 9 gregate expenditures, as estimated under
 10 section 1859D(c)(8) for the year involved;
 11 exceeds

12 “(ii) the monthly premium rate under
 13 section 1859D(d) for the month involved.

14 “MEDICARE PRESCRIPTION MEDICINE ADVISORY
 15 COMMITTEE

16 “SEC. 1859H. (a) ESTABLISHMENT OF COM-
 17 MITTEE.—There is established a Medicare Prescription
 18 Medicine Advisory Committee (in this section referred to
 19 as the ‘Committee’).

20 “(b) FUNCTIONS OF COMMITTEE.—The Committee
 21 shall advise the Secretary on policies related to—

22 “(1) the development of guidelines for the im-
 23 plementation and administration of the outpatient
 24 prescription medicine benefit program under this
 25 part; and

26 “(2) the development of—

1 “(A) standards required of pharmacy con-
2 tractors under section 1859D(c)(5) for deter-
3 mining if a medicine is as effective for an en-
4 rollee or has a significant adverse effect on an
5 enrollee under this part;

6 “(B) standards for—

7 “(i) defining therapeutic classes;

8 “(ii) adding new therapeutic classes;

9 “(iii) assigning to such classes covered
10 outpatient prescription medicines; and

11 “(iv) identifying breakthrough medi-
12 cines;

13 “(C) procedures to evaluate the bids sub-
14 mitted by pharmacy contractors under this
15 part;

16 “(D) procedures for negotiations, and
17 standards for entering into contracts, with
18 manufacturers, including identifying medicines
19 or classes of medicines where Secretarial nego-
20 tiation is most likely to yield savings under this
21 part significantly above those that which could
22 be achieved by a pharmacy contractor; and

23 “(E) procedures to ensure that pharmacy
24 contractors with a contract under this part are

1 in compliance with the requirements under this
2 part.

3 For purposes of this part, a medicine is a ‘breakthrough
4 medicine’ if the Secretary, in consultation with the Com-
5 mittee, determines it is a new product that will make a
6 significant and major improvement by reducing physical
7 or mental illness, reducing mortality, or reducing dis-
8 ability, and that no other product is available to bene-
9 ficiaries that achieves similar results for the same condi-
10 tion. The Committee may consider cost-effectiveness in es-
11 tablishing standards for defining therapeutic classes and
12 assigning drugs to such classes under subparagraph (B).

13 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
14 MITTEE.—

15 “(1) STRUCTURE.—The Committee shall be
16 composed of 19 members who shall be appointed by
17 the Secretary.

18 “(2) MEMBERSHIP.—

19 “(A) IN GENERAL.—The members of the
20 Committee shall be chosen on the basis of their
21 integrity, impartiality, and good judgment, and
22 shall be individuals who are, by reason of their
23 education, experience, and attainments, excep-
24 tionally qualified to perform the duties of mem-
25 bers of the Committee.

1 “(B) SPECIFIC MEMBERS.—Of the mem-
2 bers appointed under paragraph (1)—

3 “(i) 5 shall be chosen to represent
4 practicing physicians, 2 of whom shall be
5 gerontologists;

6 “(ii) 2 shall be chosen to represent
7 practicing nurse practitioners;

8 “(iii) 4 shall be chosen to represent
9 practicing pharmacists;

10 “(iv) 1 shall be chosen to represent
11 the Centers for Medicare & Medicaid Serv-
12 ices;

13 “(v) 4 shall be chosen to represent ac-
14 tuaries, pharmacoeconomists, researchers,
15 and other appropriate experts;

16 “(vi) 1 shall be chosen to represent
17 emerging medicine technologies;

18 “(vii) 1 shall be chosen to represent
19 the Food and Drug Administration; and

20 “(viii) 1 shall be chosen to represent
21 individuals enrolled under this part.

22 “(d) TERMS OF APPOINTMENT.—Each member of
23 the Committee shall serve for a term determined appro-
24 priate by the Secretary. The terms of service of the mem-
25 bers initially appointed shall begin on January 1, 2005.

1 “(e) CHAIRPERSON.—The Secretary shall designate
2 a member of the Committee as Chairperson. The term as
3 Chairperson shall be for a 1-year period.

4 “(f) COMMITTEE PERSONNEL MATTERS.—

5 “(1) MEMBERS.—

6 “(A) COMPENSATION.—Each member of
7 the Committee who is not an officer or em-
8 ployee of the Federal Government shall be com-
9 pensated at a rate equal to the daily equivalent
10 of the annual rate of basic pay prescribed for
11 level IV of the Executive Schedule under section
12 5315 of title 5, United States Code, for each
13 day (including travel time) during which such
14 member is engaged in the performance of the
15 duties of the Committee. All members of the
16 Committee who are officers or employees of the
17 United States shall serve without compensation
18 in addition to that received for their services as
19 officers or employees of the United States.

20 “(B) TRAVEL EXPENSES.—The members
21 of the Committee shall be allowed travel ex-
22 penses, including per diem in lieu of subsist-
23 ence, at rates authorized for employees of agen-
24 cies under subchapter I of chapter 57 of title 5,
25 United States Code, while away from their

1 homes or regular places of business in the per-
2 formance of services for the Committee.

3 “(2) STAFF.—The Committee may appoint
4 such personnel as the Committee considers appro-
5 priate.

6 “(g) OPERATION OF THE COMMITTEE.—

7 “(1) MEETINGS.—The Committee shall meet at
8 the call of the Chairperson (after consultation with
9 the other members of the Committee) not less often
10 than quarterly to consider a specific agenda of
11 issues, as determined by the Chairperson after such
12 consultation.

13 “(2) QUORUM.—Ten members of the Com-
14 mittee shall constitute a quorum for purposes of
15 conducting business.

16 “(h) FEDERAL ADVISORY COMMITTEE ACT.—Section
17 14 of the Federal Advisory Committee Act (5 U.S.C.
18 App.) shall not apply to the Committee.

19 “(i) TRANSFER OF PERSONNEL, RESOURCES, AND
20 ASSETS.—For purposes of carrying out its duties, the Sec-
21 retary and the Committee may provide for the transfer
22 to the Committee of such civil service personnel in the em-
23 ploy of the Department of Health and Human Services
24 (including the Centers for Medicare & Medicaid Services),

1 and such resources and assets of the Department used in
2 carrying out this title, as the Committee requires.

3 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated such sums as may be
5 necessary to carry out the purposes of this section.”.

6 (b) APPLICATION OF GENERAL EXCLUSIONS FROM
7 COVERAGE.—

8 (1) APPLICATION TO PART D.—Section 1862(a)
9 (42 U.S.C. 1395y(a)) is amended in the matter pre-
10 ceding paragraph (1) by striking “part A or part B”
11 and inserting “part A, B, or D”.

12 (2) PRESCRIPTION MEDICINES NOT EXCLUDED
13 FROM COVERAGE IF APPROPRIATELY PRESCRIBED.—
14 Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is
15 amended—

16 (A) in subparagraph (H), by striking
17 “and” at the end;

18 (B) in subparagraph (I), by striking the
19 semicolon at the end and inserting “, and”; and

20 (C) by adding at the end the following new
21 subparagraph:

22 “(J) in the case of prescription medicines
23 covered under part D, which are not prescribed
24 in accordance with such part;”.

1 (c) CONFORMING AMENDMENTS.—(1) Part C of title
2 XVIII is amended—

3 (A) in section 1851(a)(2)(B) (42 U.S.C.
4 1395w-21(a)(2)(B)), by striking “1859(b)(3)” and
5 inserting “1858(b)(3)”;

6 (B) in section 1851(a)(2)(C) (42 U.S.C.
7 1395w-21(a)(2)(C)), by striking “1859(b)(2)” and
8 inserting “1858(b)(2)”;

9 (C) in section 1852(a)(1) (42 U.S.C. 1395w-
10 22(a)(1)), by striking “1859(b)(3)” and inserting
11 “1858(b)(3)”;

12 (D) in section 1852(a)(3)(B)(ii) (42 U.S.C.
13 1395w-22(a)(3)(B)(ii)), by striking
14 “1859(b)(2)(B)” and inserting “1858(b)(2)(B)”;

15 (E) in section 1853(a)(1)(A) (42 U.S.C.
16 1395w-23(a)(1)(A)), by striking “1859(e)(4)” and
17 inserting “1858(e)(4)”;

18 (F) in section 1853(a)(3)(D) (42 U.S.C.
19 1395w-23(a)(3)(D)), by striking “1859(e)(4)” and
20 inserting “1858(e)(4)”.

21 (2) Section 1171(a)(5)(D) (42 U.S.C.
22 1320d(a)(5)(D)) is amended by striking “or (C)” and in-
23 serting “(C), or (D)”.

1 **SEC. 102. PROVISION OF MEDICARE OUTPATIENT PRE-**
2 **SCRIPTION MEDICINE COVERAGE UNDER**
3 **THE MEDICARE+CHOICE PROGRAM.**

4 (a) REQUIRING AVAILABILITY OF AN ACTUARIALLY
5 EQUIVALENT PRESCRIPTION MEDICINE BENEFIT.—Sec-
6 tion 1851 (42 U.S.C. 1395w–21) is amended by adding
7 at the end the following new subsection:

8 “(j) AVAILABILITY OF PRESCRIPTION MEDICINE
9 BENEFITS.—

10 “(1) IN GENERAL.—Notwithstanding any other
11 provision of this part, each Medicare+Choice organi-
12 zation that makes available a Medicare+Choice plan
13 described in section 1851(a)(2)(A) shall make avail-
14 able such a plan that offers coverage of covered out-
15 patient prescription medicines that is at least actu-
16 arially equivalent to the benefits provided under part
17 D. Information respecting such benefits shall be
18 made available in the same manner as information
19 on other benefits provided under this part is made
20 available. Nothing in this paragraph shall be con-
21 strued as requiring the offering of such coverage
22 separate from coverage that includes benefits under
23 parts A and B.

24 “(2) TREATMENT OF PRESCRIPTION MEDICINE
25 ENROLLEES.—In the case of a Medicare+Choice eli-
26 gible individual who is enrolled under part D, the

1 benefits described in paragraph (1) shall be treated
2 in the same manner as benefits described in part B
3 for purposes of coverage and payment and any ref-
4 erence in this part to the Federal Supplementary
5 Medical Insurance Trust Fund shall be deemed, with
6 respect to such benefits, to be a reference to the
7 Federal Medicare Prescription Medicine Trust
8 Fund.”.

9 (b) APPLICATION OF QUALITY STANDARDS.—Section
10 1852(e)(2)(A) (42 U.S.C. 1395w–22(e)(2)(A)) is amend-
11 ed—

12 (1) by striking “and” at the end of clause (xi);

13 (2) by striking the period at the end of clause
14 (xii) and inserting “, and”; and

15 (3) by adding at the end the following new
16 clause:

17 “(xiii) comply with the standards, and
18 apply the programs, under section
19 1859B(b) for covered outpatient prescrip-
20 tion medicines under the plan.”.

21 (c) PAYMENT SEPARATE FROM PAYMENT FOR PART
22 A AND B BENEFITS.—Section 1853 (42 U.S.C. 1395w–
23 23) is amended—

24 (1) in subsection (a)(1)(A), by striking “and
25 (i)” and inserting “(i), and (j)”; and

1 (2) by adding at the end the following new sub-
2 section:

3 “(j) PAYMENT FOR PRESCRIPTION MEDICINE COV-
4 ERAGE OPTION.—

5 “(1) IN GENERAL.—In the case of a
6 Medicare+Choice plan that provides prescription
7 medicine benefits described in section 1851(j)(1),
8 the amount of payment otherwise made to the
9 Medicare+Choice organization offering the plan
10 shall be increased by the amount described in para-
11 graph (2). Such payments shall be made in the same
12 manner and time as the amount otherwise paid, but
13 such amount shall be payable from the Federal
14 Medicare Prescription Medicine Trust Fund.

15 “(2) AMOUNT.—The amount described in this
16 paragraph is the monthly Government contribution
17 amount computed under section 1859G(c)(2)(B),
18 but subject to adjustment under paragraph (3).
19 Such amount shall be uniform geographically and
20 shall not vary based on the Medicare+Choice pay-
21 ment area involved.

22 “(3) RISK ADJUSTMENT.—The Secretary shall
23 establish a methodology for the adjustment of the
24 payment amount under this subsection in a manner
25 that takes into account the relative risks for use of

1 outpatient prescription medicines by
 2 Medicare+Choice enrollees. Such methodology shall
 3 be designed in a manner so that the total payments
 4 under this title (including part D) are not changed
 5 as a result of the application of such methodology.”.

6 (d) SEPARATE APPLICATION OF ADJUSTED COMMU-
 7 NITY RATE (ACR).—Section 1854 (42 U.S.C. 1395w–24)
 8 is amended by adding at the end the following:

9 “(i) APPLICATION TO PRESCRIPTION MEDICINE COV-
 10 ERAGE.—The Secretary shall apply the previous provisions
 11 of this section (including the computation of the adjusted
 12 community rate) separately with respect to prescription
 13 medicine benefits described in section 1851(j)(1).”.

14 (e) CONFORMING AMENDMENTS.—

15 (1) Section 1851 (42 U.S.C. 1395w–21) is
 16 amended—

17 (A) in subsection (a)(1)(A), by striking
 18 “parts A and B” and inserting “parts A, B,
 19 and D”; and

20 (B) in subsection (i) by inserting “(and, if
 21 applicable, part D)” after “parts A and B”.

22 (2) Section 1852(a)(1)(A) (42 U.S.C. 1395w–
 23 22(a)(1)(A)) is amended by inserting “(and under
 24 part D to individuals also enrolled under such part)”
 25 after “parts A and B”.

1 (3) Section 1852(d)(1) (42 U.S.C. 1395w–
2 22(d)(1)) is amended—

3 (A) by striking “and” at the end of sub-
4 paragraph (D);

5 (B) by striking the period at the end of
6 subparagraph (E) and inserting “; and”; and

7 (C) by adding at the end the following:

8 “(F) the plan for part D benefits guaran-
9 tees coverage of any specifically named pre-
10 scription medicine for an enrollee to the extent
11 that it would be required to be covered under
12 part D.

13 In carrying out subparagraph (F), a
14 Medicare+Choice organization has the same author-
15 ity to enter into contracts with respect to coverage
16 of preferred medicines as the Secretary has under
17 part D, but subject to an independent contractor ap-
18 peal or other appeal process that would be applicable
19 to determinations by such a pharmacy contractor
20 consistent with section 1859D(c)(5).”.

21 (f) LIMITATION ON COST-SHARING.—Section
22 1854(e) (42 U.S.C. 1395w–24(e)) is amended by adding
23 at the end the following new paragraph:

24 “(5) LIMITATION ON COST-SHARING.—In no
25 event may a Medicare+Choice organization include

1 a requirement that an enrollee pay cost-sharing in
2 excess of the cost-sharing otherwise permitted under
3 part D.”.

4 **SEC. 103. MEDIGAP REVISIONS.**

5 (a) REQUIRED COVERAGE OF COVERED OUTPATIENT
6 PRESCRIPTION MEDICINES.—Section 1882(p)(2)(B) (42
7 U.S.C. 1395ss(p)(2)(B)) is amended by inserting before
8 “and” at the end the following: “including a requirement
9 that an appropriate number of policies provide coverage
10 of medicines which complements but does not duplicate
11 the medicine benefits that beneficiaries are otherwise eligi-
12 ble for benefits under part D of this title (with the Sec-
13 retary and the National Association of Insurance Commis-
14 sioners determining the appropriate level of medicine ben-
15 efits that each benefit package must provide and ensuring
16 that policies providing such coverage are affordable for
17 beneficiaries;”.

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall take effect on January 1, 2006.

20 (c) TRANSITION PROVISIONS.—

21 (1) IN GENERAL.—If the Secretary of Health
22 and Human Services identifies a State as requiring
23 a change to its statutes or regulations to conform its
24 regulatory program to the amendments made by this
25 section, the State regulatory program shall not be

1 considered to be out of compliance with the require-
2 ments of section 1882 of the Social Security Act due
3 solely to failure to make such change until the date
4 specified in paragraph (4).

5 (2) NAIC STANDARDS.—If, within 9 months
6 after the date of enactment of this Act, the National
7 Association of Insurance Commissioners (in this
8 subsection referred to as the “NAIC”) modifies its
9 NAIC Model Regulation relating to section 1882 of
10 the Social Security Act (referred to in such section
11 as the 1991 NAIC Model Regulation, as subse-
12 quently modified) to conform to the amendments
13 made by this section, such revised regulation incor-
14 porating the modifications shall be considered to be
15 the applicable NAIC model regulation (including the
16 revised NAIC model regulation and the 1991 NAIC
17 Model Regulation) for the purposes of such section.

18 (3) SECRETARY STANDARDS.—If the NAIC
19 does not make the modifications described in para-
20 graph (2) within the period specified in such para-
21 graph, the Secretary of Health and Human Services
22 shall make the modifications described in such para-
23 graph and such revised regulation incorporating the
24 modifications shall be considered to be the appro-
25 priate regulation for the purposes of such section.

1 (4) DATE SPECIFIED.—

2 (A) IN GENERAL.—Subject to subpara-
3 graph (B), the date specified in this paragraph
4 for a State is the earlier of—

5 (i) the date the State changes its stat-
6 utes or regulations to conform its regu-
7 latory program to the changes made by
8 this section; or

9 (ii) 1 year after the date the NAIC or
10 the Secretary first makes the modifications
11 under paragraph (2) or (3), respectively.

12 (B) ADDITIONAL LEGISLATIVE ACTION RE-
13 QUIRED.—In the case of a State which the Sec-
14 retary identifies as—

15 (i) requiring State legislation (other
16 than legislation appropriating funds) to
17 conform its regulatory program to the
18 changes made in this section; but

19 (ii) having a legislature which is not
20 scheduled to meet in 2004 in a legislative
21 session in which such legislation may be
22 considered;

23 the date specified in this paragraph is the first
24 day of the first calendar quarter beginning after
25 the close of the first legislative session of the

1 State legislature that begins on or after Janu-
 2 ary 1, 2004. For purposes of the previous sen-
 3 tence, in the case of a State that has a 2-year
 4 legislative session, each year of such session
 5 shall be deemed to be a separate regular session
 6 of the State legislature.

7 **SEC. 104. TRANSITIONAL ASSISTANCE FOR LOW INCOME**
 8 **BENEFICIARIES.**

9 (a) QMB COVERAGE OF PREMIUMS AND COST-SHAR-
 10 ING.—Section 1905(p)(3) (42 U.S.C. 1396d(p)(3)) is
 11 amended—

12 (1) in subparagraph (A)—

13 (A) by striking “and” at the end of clause

14 (i),

15 (B) by adding “and” at the end of clause

16 (ii), and

17 (C) by adding at the end the following new
 18 clause:

19 “(iii) premiums under section 1859D(d).”;

20 (2) in subparagraph (B), by inserting “and sec-
 21 tion 1859D(c)(3)(B) and 1859D(c)(3)(C)(i)” after
 22 “1813”; and

23 (3) in subparagraph (C), by striking “and sec-
 24 tion 1833(b)” and inserting “, section 1833(b), and
 25 section 1859D(c)(2)”.

1 (b) EXPANDED SLMB ELIGIBILITY.—Section
2 1902(a)(10)(E) (42 U.S.C. 1396a(a)(10)(E)) is amend-
3 ed—

4 (1) by striking “and” at the end of clause (iii);

5 (2) by adding “and” at the end of clause (iv);

6 and

7 (3) by adding at the end the following new
8 clause:

9 “(v)(I) for making medical assistance
10 available for medicare cost-sharing described in
11 section 1905(p)(3)(A)(iii) and medicare cost-
12 sharing described in section 1905(p)(3)(B) and
13 section 1905(p)(3)(C) but only insofar as it re-
14 lates to benefits provided under part D of title
15 XVIII, subject to section 1905(p)(4), for indi-
16 viduals (other than qualified medicare bene-
17 ficiaries) who are enrolled under part D of title
18 XVIII and are described in section
19 1905(p)(1)(B) or would be so described but for
20 the fact that their income exceeds 100 percent,
21 but is less than 150 percent, of the official pov-
22 erty line (referred to in such section) for a fam-
23 ily of the size involved;

24 “(II) subject to section 1905(p)(4), for in-
25 dividuals (other than qualified medicare bene-

1 ficiaries and individuals described in subclause
2 (I)) who are enrolled under part D of title
3 XVIII and would be described in section
4 1905(p)(1)(B) but for the fact that their in-
5 come exceeds 150 percent, but is less than 175
6 percent, of the official poverty line (referred to
7 in such section) for a family of the size in-
8 volved, for making medical assistance available
9 for medicare cost-sharing described in section
10 1905(p)(3)(A)(iii) and medicare cost-sharing
11 described in section 1905(p)(3)(B) and section
12 1905(p)(3)(C) but only insofar as it relates to
13 benefits provided under part D of title XVIII,
14 and the assistance for medicare cost-sharing de-
15 scribed in section 1905(p)(3)(A)(iii) is reduced
16 (on a sliding scale based on income) from 100
17 percent to 0 percent as the income increases
18 from 150 percent to 175 percent of such pov-
19 erty line;”.

20 (c) FEDERAL FINANCING.—The third sentence of
21 section 1905(b) (42 U.S.C. 1396d(b)) is amended by in-
22 serting before the period at the end the following: “and
23 with respect to amounts expended that are attributable to
24 section 1902(a)(10)(E)(v) (other than for individuals de-
25 scribed in section 1905(p)(1)(B))”.

1 (d) TREATMENT OF TERRITORIES.—

2 (1) IN GENERAL.—Section 1905(p) (42 U.S.C.
3 1396d(p)) is amended—

4 (A) by redesignating paragraphs (5) and
5 (6) as paragraphs (6) and (7), respectively; and

6 (B) by inserting after paragraph (4) the
7 following new paragraph:

8 “(5)(A) In the case of a State, other than the 50
9 States and the District of Columbia—

10 “(i) the provisions of paragraph (3) insofar as
11 they relate to section 1859D and the provisions of
12 section 1902(a)(10)(E)(v) shall not apply to resi-
13 dents of such State; and

14 “(ii) if the State establishes a plan described in
15 subparagraph (B) (for providing medical assistance
16 with respect to the provision of prescription medi-
17 cines to medicare beneficiaries), the amount other-
18 wise determined under section 1108(f) (as increased
19 under section 1108(g)) for the State shall be in-
20 creased by the amount specified in subparagraph
21 (C).

22 “(B) The plan described in this subparagraph is a
23 plan that—

24 “(i) provides medical assistance with respect to
25 the provision of covered outpatient medicines (as de-

1 fined in section 1859D(b)) to low-income medicare
 2 beneficiaries; and

3 “(ii) assures that additional amounts received
 4 by the State that are attributable to the operation
 5 of this paragraph are used only for such assistance.

6 “(C)(i) The amount specified in this subparagraph
 7 for a State for a year is equal to the product of—

8 “(I) the aggregate amount specified in clause
 9 (ii); and

10 “(II) the amount specified in section 1108(g)(1)
 11 for that State, divided by the sum of the amounts
 12 specified in such section for all such States.

13 “(ii) The aggregate amount specified in this clause
 14 for—

15 “(I) 2006, is equal to \$25,000,000; or

16 “(II) a subsequent year, is equal to the aggre-
 17 gate amount specified in this clause for the previous
 18 year increased by annual percentage increase speci-
 19 fied in section 1859D(c)(8)(B) for the year involved.

20 “(D) The Secretary shall submit to Congress a report
 21 on the application of this paragraph and may include in
 22 the report such recommendations as the Secretary deems
 23 appropriate.”.

24 (2) CONFORMING AMENDMENT.—Section
 25 1108(f) (42 U.S.C. 1308(f)) is amended by inserting

1 “and section 1905(p)(5)(A)(ii)” after “Subject to
2 subsection (g)”.

3 (e) APPLICATION OF COST-SHARING.—Section
4 1902(n)(2) (42 U.S.C. 1396a(n)(2)) is amended by add-
5 ing at the end the following: “The previous sentence shall
6 not apply to medicare cost-sharing relating to benefits
7 under part D of title XVIII.”.

8 (f) EFFECTIVE DATE.—The amendments made by
9 this section apply to medical assistance for premiums and
10 cost-sharing incurred on or after January 1, 2006, with
11 regard to whether regulations to implement such amend-
12 ments are promulgated by such date.

13 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**
14 **MEDICARE PAYMENT ADVISORY COMMISSION**
15 **(MEDPAC).**

16 (a) EXPANSION OF MEMBERSHIP.—

17 (1) IN GENERAL.—Section 1805(c) (42 U.S.C.
18 1395b–6(c)) is amended—

19 (A) in paragraph (1), by striking “17” and
20 inserting “19”; and

21 (B) in paragraph (2)(B), by inserting “ex-
22 perts in the area of pharmacology and prescrip-
23 tion medicine benefit programs,” after “other
24 health professionals,”.

1 (2) INITIAL TERMS OF ADDITIONAL MEM-
2 BERS.—

3 (A) IN GENERAL.—For purposes of stag-
4 gering the initial terms of members of the
5 Medicare Payment Advisory Commission under
6 section 1805(c)(3) of the Social Security Act
7 (42 U.S.C. 1395b–6(c)(3)), the initial terms of
8 the 2 additional members of the Commission
9 provided for by the amendment under para-
10 graph (1)(A) are as follows:

11 (i) One member shall be appointed for
12 1 year.

13 (ii) One member shall be appointed
14 for 2 years.

15 (B) COMMENCEMENT OF TERMS.—Such
16 terms shall begin on January 1, 2004.

17 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) (42
18 U.S.C. 1395b–6(b)(2)) is amended by adding at the end
19 the following new subparagraph:

20 “(D) PRESCRIPTION MEDICINE BENEFIT
21 PROGRAM.—Specifically, the Commission shall
22 review, with respect to the prescription medicine
23 benefit program under part D, the following:

1 “(i) The methodologies used for the
2 management of costs and utilization of
3 prescription medicines.

4 “(ii) The prices negotiated and paid,
5 including trends in such prices and appli-
6 cable discounts and comparisons with
7 prices under section 1859E(a)(2)(E).

8 “(iii) The relationship of pharmacy
9 acquisition costs to the prices so negotiated
10 and paid.

11 “(iv) The methodologies used to en-
12 sure access to covered outpatient prescrip-
13 tion medicines and to ensure quality in the
14 appropriate dispensing and utilization of
15 such medicines.

16 “(v) The impact of the program on
17 promoting the development of break-
18 through medicines.”.

1 **TITLE II—AFFORDABLE**
2 **PHARMACEUTICALS**
3 **Subtitle A—Greater Access to**
4 **Affordable Pharmaceuticals**

5 **SEC. 201. ACCELERATED GENERIC DRUG COMPETITION.**

6 (a) IN GENERAL.—Section 505(j)(5) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is
8 amended—

9 (1) in subparagraph (B)(iv), by striking sub-
10 clause (II) and inserting the following:

11 “(II) the earlier of—

12 “(aa) the date of a final decision of a
13 court in an action described in clause
14 (iii)(II) (from which no appeal can or has
15 been taken, other than a petition to the
16 Supreme Court for a writ of certiorari)
17 holding the patent that is the subject of
18 the certification to be invalid or not in-
19 fringed; or

20 “(bb) the date of a settlement order
21 or consent decree in such an action signed
22 by a Federal judge that enters a final
23 judgment and includes a finding that the
24 patent that is the subject of the certifi-
25 cation is invalid or not infringed;”;

1 (2) by redesignating subparagraphs (C) and
2 (D) as subparagraphs (E) and (F), respectively; and

3 (3) by inserting before subparagraph (E) (as so
4 redesignated) the following subparagraph:

5 “(D)(i) The 180-day period described in subpara-
6 graph (B)(iv) shall be forfeited by the previous applicant
7 if—

8 “(I) the previous applicant fails to market the
9 drug by the later of the date 60 days after the date
10 on which the approval of the application for the drug
11 is made effective under subparagraph (B)(iii) or, if
12 such approval has been made effective, and if an ac-
13 tion has been brought against the previous applicant
14 for infringement of a patent subject to a certifi-
15 cation under paragraph (2)(A)(vii)(IV), or an action
16 has been brought by the previous applicant for a de-
17 claratory judgment that such a patent is invalid or
18 not infringed, the date 60 days after the date of a
19 final decision in such action, if there is no other
20 such action pending by or against the previous appli-
21 cant; except, however, that either of such dates may
22 be extended due to extraordinary or unusual cir-
23 cumstances, as determined by the Secretary;

24 “(II) the previous applicant withdraws the ap-
25 plication;

1 “(III) the previous applicant amends the certifi-
2 cation from a certification under subclause (IV) of
3 paragraph (2)(A)(vii) to a certification under sub-
4 clause (III) of such paragraph, either voluntarily or
5 as a result of a settlement or defeat in patent litiga-
6 tion;

7 “(IV) the previous applicant fails to obtain ten-
8 tative approval of the application within 30 months
9 after the date on which the application is filed, un-
10 less the failure is caused by—

11 “(aa) a change in the requirements for
12 tentative approval of the application imposed
13 after the date on which the application was
14 filed; or

15 “(bb) other extraordinary or unusual cir-
16 cumstances, as determined by the Secretary;

17 “(V) in a case in which, after the date on which
18 the previous application was submitted under this
19 subsection, new patent information is submitted
20 under subsection (c)(2) for the listed drug for a pat-
21 ent for which certification or a method of use state-
22 ment is required under paragraph (2)(A), the pre-
23 vious applicant fails to submit no later than 60 days
24 from the date the applicant receives notice from the
25 Secretary under paragraph (7)(A)(iii) of the submis-

1 sion of the new patent information either a certifi-
2 cation described in paragraph (2)(A)(vii)(IV) or a
3 statement that the method of use patent does not
4 claim a use for which the applicant is seeking ap-
5 proval under this subsection in accordance with
6 paragraph (2)(A)(viii); except, however, that such
7 date may be extended due to extraordinary or un-
8 usual circumstances, as determined by the Secretary;
9 or

10 “(VI) the previous applicant is determined by
11 the Secretary, after a fair and sufficient hearing and
12 in consultation with the Federal Trade Commission,
13 to have engaged in anticompetitive or collusive con-
14 duct, or any other conduct intended to unfairly mo-
15 nopolize the commercial manufacturing of the drug
16 of the application.

17 “(ii) If under clause (i) the previous applicant re-
18 ferred to in subparagraph (B)(iv) forfeits the 180-day pe-
19 riod described in such subparagraph, such period shall be-
20 come available to the next applicant submitting an appli-
21 cation containing a certification under paragraph
22 (2)(A)(vii)(IV) if—

23 “(I) no action described in subparagraph
24 (B)(iii)(II) was brought against or by the previous
25 applicant, or such an action was brought but did not

1 result in a final judgment that included a finding
2 that the patent involved is invalid; and

3 “(II) an action described in subparagraph
4 (B)(iii)(II) is brought against or by the next appli-
5 cant, and such action results in a final judgment
6 that includes a finding that the patent involved is in-
7 valid.

8 “(iii) The 180-day period described in subparagraph
9 (B)(iv) shall be available only to—

10 “(I) the previous applicant submitting an appli-
11 cation for a drug under this subsection containing a
12 certification described in paragraph (2)(A)(vii)(IV)
13 with respect to any patent; or

14 “(II) under clause (ii), the next applicant sub-
15 mitting an application for a drug under this sub-
16 section containing such a certification with respect
17 to any patent;

18 even if an application has been submitted for the drug
19 under this subsection containing such a certification with
20 respect to a different patent.

21 “(iv) The 180-day period described in subparagraph
22 (B)(iv) for an application containing a certification de-
23 scribed in paragraph (2)(A)(vii)(IV) shall apply only if an
24 action is brought for infringement of a patent that is the
25 subject of the certification or the applicant brings an ac-

tion (not later than 60 days after the date on which the notice provided under paragraph (2)(B)(ii) was received) against the holder of the approved application for the listed drug.”.

(b) **EFFECTIVE DATE.**—The amendment made by this section shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of the enactment of this Act.

SEC. 202. PATENT CERTIFICATION.

(a) **ABBREVIATED NEW DRUG APPLICATIONS.**—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B), by striking clause (iii) and inserting the following:

“(iii)(I) If the applicant made a certification described in paragraph (2)(A)(vii)(IV) and—

“(aa) no action is brought for infringement of a patent that is the subject of the certification before the expiration of the 45-day period beginning on the date on which the notice provided under paragraph (2)(B)(ii) was received; and

1 “(bb) the applicant does not bring an ac-
2 tion for declaratory judgment authorized in
3 subclause (II) before the expiration of the 60-
4 day period beginning on the date on which the
5 notice provided under paragraph (2)(B)(ii) was
6 received;

7 the approval shall be made effective on the expira-
8 tion of 60 days after the date on which the notice
9 provided under paragraph (2)(B)(ii) was received,
10 provided none of the conditions for denial of ap-
11 proval in paragraph (4) apply.

12 “(II) With respect to an applicant who made a
13 certification described in paragraph (2)(A)(vii)(IV),
14 if an action referred to in item (aa) of subclause (I)
15 is brought before the expiration of the period de-
16 scribed in such item, or if the applicant brings an
17 action for declaratory judgment of invalidity or non-
18 infringement of such patent (which action is hereby
19 authorized) before the expiration of the period de-
20 scribed in item (bb) of such subclause, the approval
21 shall, provided none of the conditions for denial of
22 approval in paragraph (4) apply, be made effective
23 in accordance with the following:

24 “(aa) If the action is an action referred to
25 in subclause (I)(aa), and neither the holder of

1 the approved application nor the owner of the
2 patent seek a preliminary injunction prohibiting
3 the applicant from engaging in the commercial
4 manufacture or sale (or both) of the drug, the
5 approval shall be made effective on the expira-
6 tion of 60 days after the date on which the no-
7 tice provided under paragraph (2)(B)(ii) was
8 received.

9 “(bb) If the action is an action referred to
10 in subclause (I)(aa), and such a preliminary in-
11 junction is sought and the court denies the mo-
12 tion, the approval shall be made effective on the
13 date on which the court denies the injunction.

14 “(cc) If neither item (aa) nor (bb) applies,
15 and the holding of the court in the decision in
16 the action is that the patent is invalid or was
17 not infringed, the approval shall be made effec-
18 tive on the date of the decision of the court.

19 “(dd) If neither item (aa) nor (bb) applies,
20 and the holding of the court in the decision in
21 the action is that the patent was infringed, the
22 approval shall be made effective on such date as
23 the court orders under section 271(e)(4)(A) of
24 title 35, United States Code.”; and

1 (2) by inserting before subparagraph (D) (as
2 added by section 201(a)(3)) the following subpara-
3 graph:

4 “(C) With respect to a civil action described in sub-
5 paragraph (B)(iii)(II):

6 “(i) Each of the parties shall reasonably cooper-
7 ate in expediting the action.

8 “(ii) If the notice under paragraph (2)(B)(ii)
9 contains an address for the receipt of expedited noti-
10 fication of such an action, the plaintiff shall, on the
11 date the complaint is filed in the court, simulta-
12 neously cause a notification of such action to be de-
13 livered to such address by the next business day.

14 “(iii) An action for a declaratory judgment au-
15 thorized in such subparagraph may not be brought
16 by the applicant until the expiration of 45 days after
17 the date the notice provided under paragraph
18 (2)(B)(ii) was received, except that if information on
19 the patent involved has been published under sub-
20 section (c)(2) for at least one year after the date on
21 which the application under this subsection was filed
22 in relation to the listed drug involved, the applicant
23 may immediately bring such an action for declara-
24 tory judgment.

1 “(iv) Any such action shall be brought in the
2 judicial district in which the defendant has its prin-
3 cipal place of business or a regular and established
4 place of business.”.

5 (b) NEW DRUG APPLICATIONS.—Section 505(c)(3)
6 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355(c)(3)) is amended by striking subparagraph (C) and
8 inserting the following:

9 “(C)(i)(I) If the applicant made a certification
10 described in subsection (b)(2)(A)(iv) and—

11 “(aa) no action is brought for infringement
12 of a patent that is the subject of the certifi-
13 cation before the expiration of the 45-day pe-
14 riod beginning on the date on which the notice
15 provided under subsection (b)(3)(B) was re-
16 ceived; and

17 “(bb) the applicant does not bring an ac-
18 tion for declaratory judgment authorized in
19 subclause (II) before the expiration of the 60-
20 day period beginning on the date on which the
21 notice provided under subsection (b)(3)(B) was
22 received;

23 the approval shall be made effective on the expira-
24 tion of 60 days after the date on which the notice
25 provided under subsection (b)(3)(B) was received,

1 provided that none of the conditions for refusal of
2 approval in subsection (d) apply.

3 “(II) With respect to an applicant who made a
4 certification described in subsection (b)(2)(A)(iv), if
5 an action referred to in item (aa) of subclause (I)
6 is brought before the expiration of the period de-
7 scribed in such item, or if the applicant brings an
8 action for declaratory judgment of invalidity or non-
9 infringement of such patent (which action is hereby
10 authorized) before the expiration of the period de-
11 scribed in item (bb) of such subclause, the approval
12 shall, provided none of the conditions for refusal of
13 approval in subsection (d) apply, be made effective
14 in accordance with the following:

15 “(aa) If the action is an action referred to
16 in subclause (I)(aa), and neither the holder of
17 the approved application nor the owner of the
18 patent seek a preliminary injunction prohibiting
19 the applicant from engaging in the commercial
20 manufacture or sale (or both) of the drug, the
21 approval shall be made effective on the expira-
22 tion of 60 days after the date on which the no-
23 tice provided under subsection (b)(3)(B) was re-
24 ceived.

1 “(bb) If the action is an action referred to
2 in subclause (I)(aa), and such a preliminary in-
3 junction is sought and the court denies the mo-
4 tion, the approval shall be made effective on the
5 date on which the court denies the injunction.

6 “(cc) If neither item (aa) nor (bb) applies,
7 and the holding of the court in the decision in
8 the action is that the patent is invalid or was
9 not infringed, the approval shall be made effec-
10 tive on the date of the decision of the court.

11 “(dd) If neither item (aa) nor (bb) applies,
12 and the holding of the court in the decision in
13 the action is that the patent was infringed, the
14 approval shall be made effective on such date as
15 the court orders under section 271(e)(4)(A) of
16 title 35, United States Code.

17 “(ii) With respect to a civil action described in
18 clause (i)(II):

19 “(I) Each of the parties shall reasonably
20 cooperate in expediting the action.

21 “(II) If the notice under subsection
22 (b)(3)(B) contains an address for the receipt of
23 expedited notification of such an action, the
24 plaintiff shall, on the date the complaint is filed
25 in the court, simultaneously cause a notification

1 of such action to be delivered to such address
2 by the next business day.

3 “(III) An action for a declaratory judg-
4 ment authorized in such clause may not be
5 brought by the applicant until the expiration of
6 45 days after the date the notice provided
7 under subsection (b)(3)(B) was received, except
8 that if information on the patent involved has
9 been published under paragraph (2) for at least
10 one year after the date on which the application
11 was filed in relation to the drug involved, the
12 applicant may immediately bring such an action
13 for declaratory judgment.

14 “(IV) Any such action shall be brought in
15 the judicial district in which the defendant has
16 its principal place of business or a regular and
17 established place of business.”.

18 (c) EFFECTIVE DATE.—The amendments made by
19 this section shall not apply to an application submitted
20 under section 505(b)(1) or 505(j) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355) before the date
22 of the enactment of this Act.

1 **SEC. 203. ADDITIONAL USES.**

2 Section 505(j) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 355(j)) is amended by adding at the
4 end the following paragraph:”

5 “(10)(A) A drug for which an application has been
6 submitted or approved under this subsection shall not be
7 considered ineligible for approval under this subsection or
8 misbranded under section 502 on the basis that the label-
9 ing of the drug omits a use or any other aspect of labeling
10 when the omitted use or other aspect is protected by pat-
11 ent or by exclusivity under clause (iii) or (iv) of paragraph
12 (5)(D).

13 “(B) Notwithstanding clauses (iii) and (iv) of para-
14 graph (5)(D), the Secretary may require that the labeling
15 of a drug approved under this subsection that omits a use
16 or other aspect of labeling as described in subparagraph
17 (A) include—

18 “(i) any statement that the Secretary considers
19 necessary for the safe use of the drug, such as ap-
20 propriate contraindications, warnings, or pre-
21 cautions; and

22 “(ii) a statement that, because of marketing ex-
23 clusivity for a manufacturer, the drug is not labeled
24 for the use.”.

1 **Subtitle B—Notification of Agree-**
2 **ments Affecting the Sale or Mar-**
3 **keting of Generic Drugs**

4 **SEC. 211. DEFINITIONS.**

5 In this subtitle:

6 (1) AGREEMENT.—The term “agreement”
7 means an agreement under section 1 of the Sherman
8 Act (15 U.S.C. 1) or section 5 of the Federal Trade
9 Commission Act (15 U.S.C. 45).

10 (2) ANTITRUST LAWS.—The term “antitrust
11 laws” has the same meaning as in section 1 of the
12 Clayton Act (15 U.S.C. 12), except that such term
13 includes section 5 of the Federal Trade Commission
14 Act (15 U.S.C. 45) to the extent that such section
15 applies to unfair methods of competition.

16 (3) ANDA.—The term “ANDA” means an Ab-
17 breviated New Drug Application, as defined under
18 section 505(j) of the Federal Food, Drug and Cos-
19 metic Act.

20 (4) BRAND NAME DRUG COMPANY.—The term
21 “brand name drug company” means a person en-
22 gaged in the manufacture or marketing of a drug
23 approved under section 505(b) of the Federal Food,
24 Drug and Cosmetic Act.

1 (5) COMMISSION.—The term “Commission”
2 means the Federal Trade Commission.

3 (6) FDA.—The term “FDA” means the United
4 States Food and Drug Administration.

5 (7) GENERIC DRUG.—The term “generic drug”
6 means a product that is the subject of an ANDA.

7 (8) GENERIC DRUG APPLICANT.—The term
8 “generic drug applicant” means a person who has
9 filed or received approval for an ANDA under sec-
10 tion 505(j) of the Federal Food, Drug and Cosmetic
11 Act.

12 (9) SECRETARY.—The term “Secretary” means
13 the Secretary of Health and Human Services.

14 **SEC. 212. NOTIFICATION OF AGREEMENTS AFFECTING THE**
15 **SALE OR MARKETING OF GENERIC DRUGS.**

16 A brand name drug company and a generic drug ap-
17 plicant that enter into an agreement regarding the sale
18 or manufacture of a generic drug that the Secretary has
19 determined is the therapeutic equivalent of a brand name
20 drug that is manufactured or marketed by that brand
21 name drug company, or for which the generic drug appli-
22 cant seeks such a determination of therapeutic equiva-
23 lence, and which agreement could have the effect of lim-
24 iting the research, development, manufacture, marketing,
25 or selling of a generic drug that has been or could be ap-

1 proved for sale by the FDA pursuant to an ANDA, shall
2 file with the Commission and the Secretary the text of
3 the agreement, an explanation of the purpose and scope
4 of the agreement, and an explanation of whether the
5 agreement could delay, restrain, limit, or in any way inter-
6 fere with the production, manufacture, or sale of the ge-
7 neric version of the drug in question.

8 **SEC. 213. FILING DEADLINES.**

9 Any notice, agreement, or other material required to
10 be filed under section 212 shall be filed with the Commis-
11 sion and the Secretary not later than 10 business days
12 after the date the agreement is executed.

13 **SEC. 214. ENFORCEMENT.**

14 (a) CIVIL FINE.—Any person, or any officer, direc-
15 tor, or partner thereof, who fails to comply with any provi-
16 sion of this subtitle shall be liable for a civil penalty of
17 not more than \$20,000 for each day during which such
18 person is in violation of this subtitle. Such penalty may
19 be recovered in a civil action brought by the United States,
20 or brought by the Commission in accordance with the pro-
21 cedures established in section 16(a)(1) of the Federal
22 Trade Commission Act (15 U.S.C. 56(a)).

23 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any
24 person, or any officer, director, partner, agent, or em-
25 ployee thereof, fails to comply with the notification re-

1 quirement under section 212 of this subtitle, the United
2 States district court may order compliance, and may grant
3 such other equitable relief as the court in its discretion
4 determines necessary or appropriate, upon application of
5 the Commission or the Assistant Attorney General.

6 **SEC. 215. RULEMAKING.**

7 The Commission, in consultation with the Secretary,
8 and with the concurrence of the Assistant Attorney Gen-
9 eral and by rule in accordance with section 553 of title
10 5, United States Code, consistent with the purposes of this
11 subtitle—

12 (1) may require that the notice described in sec-
13 tion 212 of this subtitle be in such form and contain
14 such documentary material and information relevant
15 to the agreement as is necessary and appropriate to
16 enable the Commission and the Assistant Attorney
17 General to determine whether such agreement may
18 violate the antitrust laws;

19 (2) may define the terms used in this subtitle;

20 (3) may exempt classes of persons or agree-
21 ments from the requirements of this subtitle; and

22 (4) may prescribe such other rules as may be
23 necessary and appropriate to carry out the purposes
24 of this subtitle.

1 **SEC. 216. EFFECTIVE DATES.**

2 This subtitle shall take effect 90 days after the date
3 of enactment of this Act.

○